

Celldex Therapeutics, Inc.
Form 10-Q
August 07, 2014
[Table of Contents](#)

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2014

OR

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

Commission File Number: 000-15006

CELLDEX THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Edgar Filing: Celldex Therapeutics, Inc. - Form 10-Q

Delaware
(State or other jurisdiction of incorporation or
organization)

No. 13-3191702
(I.R.S. Employer Identification No.)

Perryville III Building, 53 Frontage Road, Suite 220, Hampton, New Jersey 08827

(Address of principal executive offices) (Zip Code)

(908) 200-7500

(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. (Check one):

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 July 28, 2014, 89,403,761 shares of common stock, \$.001 par value per share, were outstanding.

Table of Contents

CELLDEX THERAPEUTICS, INC.

FORM 10-Q

Quarter Ended June 30, 2014

Table of Contents

| | Page |
|---|-------------|
| <u>Part I Financial Information</u> | |
| <u>Item 1. Unaudited Financial Statements</u> | 3 |
| <u>Condensed Consolidated Balance Sheets at June 30, 2014 and December 31, 2013</u> | 3 |
| <u>Condensed Consolidated Statements of Operations and Comprehensive Loss for the Three and Six Months Ended June 30, 2014 and 2013</u> | 4 |
| <u>Condensed Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2014 and 2013</u> | 5 |
| <u>Notes to Unaudited Condensed Consolidated Financial Statements</u> | 6 |
| <u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u> | 11 |
| <u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u> | 24 |
| <u>Item 4. Controls and Procedures</u> | 24 |
| <u>Part II Other Information</u> | |
| <u>Item 1A. Risk Factors</u> | 24 |
| <u>Item 6. Exhibits</u> | 25 |
| <u>Signatures</u> | 26 |
| <u>Exhibit Index</u> | 27 |

Table of Contents**PART I FINANCIAL INFORMATION****Item 1. Unaudited Financial Statements****CELLDEX THERAPEUTICS, INC.****CONDENSED CONSOLIDATED BALANCE SHEETS****(Unaudited)****(In thousands, except share and per share amounts)**

| | June 30, 2014 | December 31, 2013 |
|---|----------------------|--------------------------|
| ASSETS | | |
| Current Assets: | | |
| Cash and Cash Equivalents | \$ 40,797 | \$ 169,402 |
| Marketable Securities | 211,572 | 133,581 |
| Accounts and Other Receivables | 525 | 489 |
| Prepaid and Other Current Assets | 2,703 | 1,717 |
| Total Current Assets | 255,597 | 305,189 |
| Property and Equipment, Net | 10,601 | 9,973 |
| Intangible Assets, Net | 22,313 | 22,820 |
| Other Assets | 116 | 148 |
| Goodwill | 8,965 | 8,965 |
| Total Assets | \$ 297,592 | \$ 347,095 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current Liabilities: | | |
| Accounts Payable | \$ 1,187 | \$ 2,243 |
| Accrued Expenses | 17,897 | 17,179 |
| Current Portion of Long-Term Liabilities | 2,118 | 928 |
| Total Current Liabilities | 21,202 | 20,350 |
| Other Long-Term Liabilities | 11,075 | 6,950 |
| Total Liabilities | 32,277 | 27,300 |
| Commitments and Contingent Liabilities | | |
| Stockholders' Equity: | | |
| Convertible Preferred Stock, \$.01 Par Value; 3,000,000 Shares Authorized; No Shares Issued and Outstanding at June 30, 2014 and December 31, 2013 | | |
| Common Stock, \$.001 Par Value; 297,000,000 Shares Authorized; 89,396,160 and 89,246,832 Shares Issued and Outstanding at June 30, 2014 and December 31, 2013, respectively | 89 | 89 |
| Additional Paid-In Capital | 666,334 | 662,717 |
| Accumulated Other Comprehensive Income | 2,748 | 2,668 |
| Accumulated Deficit | (403,856) | (345,679) |
| Total Stockholders' Equity | 265,315 | 319,795 |
| Total Liabilities and Stockholders' Equity | \$ 297,592 | \$ 347,095 |

Edgar Filing: Celldex Therapeutics, Inc. - Form 10-Q

See accompanying notes to unaudited condensed consolidated financial statements

Table of Contents**CELLDEX THERAPEUTICS, INC.****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS****(Unaudited)****(In thousands, except per share amounts)**

| | Three Months Ended | | Six Months Ended | |
|--|---------------------------|----------------------|-------------------------|----------------------|
| | June 30, 2014 | June 30, 2013 | June 30, 2014 | June 30, 2013 |
| REVENUE: | | | | |
| Product Development and Licensing Agreements | \$ 200 | \$ 47 | \$ 235 | \$ 77 |
| Contracts and Grants | 392 | 50 | 773 | 100 |
| Product Royalties | | | | 2,334 |
| Total Revenue | 592 | 97 | 1,008 | 2,511 |
| OPERATING EXPENSE: | | | | |
| Research and Development | 24,100 | 15,090 | 51,169 | 29,180 |
| Royalty | | | | 2,334 |
| General and Administrative | 4,787 | 3,411 | 9,369 | 6,549 |
| Amortization of Acquired Intangible Assets | 254 | 254 | 507 | 507 |
| Total Operating Expense | 29,141 | 18,755 | 61,045 | 38,570 |
| Operating Loss | (28,549) | (18,658) | (60,037) | (36,059) |
| Investment and Other Income, Net | 275 | 161 | 1,860 | 540 |
| Interest Expense | | (519) | | (829) |
| Net Loss | \$ (28,274) | \$ (19,016) | \$ (58,177) | \$ (36,348) |
| Basic and Diluted Net Loss Per Common Share (Note 3) | \$ (0.32) | \$ (0.24) | \$ (0.65) | \$ (0.47) |
| Shares Used in Calculating Basic and Diluted Net Loss per Share (Note 3) | 89,361 | 80,899 | 89,316 | 77,482 |
| COMPREHENSIVE LOSS: | | | | |
| Net Loss | \$ (28,274) | \$ (19,016) | \$ (58,177) | \$ (36,348) |
| Other Comprehensive (Loss) Income: | | | | |
| Foreign Currency Translation Adjustments | (2) | (1) | (1) | (3) |
| Unrealized (Loss) Gain on Marketable Securities | 80 | (140) | 81 | (194) |
| Comprehensive Loss | \$ (28,196) | \$ (19,157) | \$ (58,097) | \$ (36,545) |

See accompanying notes to unaudited condensed consolidated financial statements

Table of Contents**CELLDEX THERAPEUTICS, INC.****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS****(Unaudited)****(In thousands)**

| | Six Months Ended | |
|---|-------------------------|----------------------|
| | June 30, 2014 | June 30, 2013 |
| Cash Flows from Operating Activities: | | |
| Net Loss | \$ (58,177) | \$ (36,348) |
| Adjustments to Reconcile Net Loss to Net Cash Used in Operating Activities: | | |
| Depreciation and Amortization | 1,161 | 943 |
| Amortization of Intangible Assets | 507 | 507 |
| Amortization and Premium of Marketable Securities | (1,436) | (1,949) |
| Gain on Sale or Disposal of Assets | | (21) |
| Stock-Based Compensation Expense | 2,761 | 1,384 |
| Non-Cash Interest Expense | | 97 |
| Changes in Operating Assets and Liabilities: | | |
| Accounts and Other Receivables | (36) | 32 |
| Prepaid and Other Current Assets | (1,825) | (424) |
| Other Assets | 32 | 250 |
| Accounts Payable and Accrued Expenses | (1,033) | 109 |
| Other Liabilities | 5,315 | 162 |
| Net Cash Used in Operating Activities | (52,731) | (35,258) |
| Cash Flows from Investing Activities: | | |
| Sales and Maturities of Marketable Securities | 50,587 | 20,582 |
| Purchases of Marketable Securities | (126,222) | (88,845) |
| Acquisition of Property and Equipment | (1,094) | (917) |
| Proceeds from Sale or Disposal of Assets | | 21 |
| Net Cash Used in Investing Activities | (76,729) | (69,159) |
| Cash Flows from Financing Activities: | | |
| Net Proceeds from Stock Issuances | | 114,187 |
| Proceeds from Issuance of Stock from Employee Benefit Plans | 856 | 2,294 |
| Payments of Term Loan | | (11,029) |
| Payments of Other Liabilities | | (29) |
| Net Cash Provided by Financing Activities | 856 | 105,423 |
| Effect of Exchange Rate Changes on Cash and Cash Equivalents | (1) | (3) |
| Net (Decrease) Increase in Cash and Cash Equivalents | (128,605) | 1,003 |
| Cash and Cash Equivalents at Beginning of Period | 169,402 | 24,897 |
| Cash and Cash Equivalents at End of Period | \$ 40,797 | \$ 25,900 |

See accompanying notes to unaudited condensed consolidated financial statements

Table of Contents

CELLDEX THERAPEUTICS, INC.

Notes to Unaudited Condensed Consolidated Financial Statements

June 30, 2014

(1) Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared by Celldex Therapeutics, Inc. (the "Company" or "Celldex") in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and reflect the operations of the Company and its wholly-owned subsidiary. All intercompany transactions have been eliminated in consolidation.

These interim financial statements do not include all the information and footnotes required by U.S. GAAP for annual financial statements and should be read in conjunction with the audited financial statements for the year ended December 31, 2013, which are included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC") on March 3, 2014. In the opinion of management, the interim financial statements reflect all normal recurring adjustments necessary to fairly state the Company's financial position and results of operations for the interim periods presented. The year-end consolidated balance sheet data presented for comparative purposes was derived from audited financial statements, but does not include all disclosures required by U.S. GAAP.

The results of operations for the interim periods are not necessarily indicative of the results of operations to be expected for any future interim period or the fiscal year ending December 31, 2014.

At June 30, 2014, the Company had cash, cash equivalents and marketable securities of \$252.4 million. The Company incurred a loss of \$58.2 million for the six months ended June 30, 2014. Net cash used in operations for the six months ended June 30, 2014 was \$52.7 million. The Company believes that the cash, cash equivalents and marketable securities at June 30, 2014 will be sufficient to meet estimated working capital requirements and fund planned operations for at least the next twelve months.

During the next twelve months, the Company may take further steps to raise additional capital to meet its long-term liquidity needs. These capital raising activities may include, but may not be limited to, one or more of the following: the licensing of technology programs with existing or new collaborative partners, possible business combinations, issuance of debt, or the issuance of common stock or other securities via private placements or public offerings. While the Company continues to seek capital through a number of means, there can be no assurance that additional financing will be available on acceptable terms, if at all, and the Company's negotiating position in capital-raising efforts may worsen as existing resources are used. There is also no assurance that the Company will be able to enter into further collaborative relationships. Additional equity financing may be dilutive to the Company's stockholders; debt financing, if available, may involve significant cash payment obligations and covenants that restrict the Company's ability to operate as a business; and licensing or strategic collaborations may result in royalties or other terms which reduce the Company's economic potential from products under development.

(2) Significant Accounting Policies

Edgar Filing: Celldex Therapeutics, Inc. - Form 10-Q

The significant accounting policies used in preparation of these condensed consolidated financial statements for the six months ended June 30, 2014 are consistent with those discussed in Note 2 to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2013, except for the adoption of new accounting standards during the first six months of 2014 as discussed below.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (FASB) or other standard setting bodies that are adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on the Company's financial position or results of operations upon adoption.

In May 2014, the FASB issued a new U.S. GAAP accounting standard that creates modifications to various other revenue accounting standards for specialized transactions and industries. The new U.S. GAAP accounting standard is intended to conform revenue accounting principles with a concurrently issued new standard under International Financial Reporting Standards, as well as, to enhance disclosures related to disaggregated revenue information. The updated guidance is effective for annual reporting periods beginning on or after December 15, 2016, and interim periods within those annual periods. Early adoption is not permitted. The Company will further study the implications of this standard in order to evaluate the expected impact on the consolidated financial statements.

[Table of Contents](#)

(3) Net Loss Per Share

Basic net loss per common share is based upon the weighted-average number of common shares outstanding during the period, excluding restricted stock that has been issued but is not yet vested. Diluted net loss per common share is based upon the weighted-average number of common shares outstanding during the period plus additional weighted-average potentially dilutive common shares outstanding during the period when the effect is dilutive. The potentially dilutive common shares that have not been included in the net loss per common share calculations because the effect would have been anti-dilutive are as follows:

| | Six months ended June 30, | |
|------------------|---------------------------|-----------|
| | 2014 | 2013 |
| Stock options | 6,961,766 | 5,005,603 |
| Restricted stock | 12,000 | 12,000 |
| | 6,973,766 | 5,017,603 |

(4) Comprehensive Loss

The changes in Accumulated Other Comprehensive Income by component for the three and six months ended June 30, 2014 are summarized below. No amounts were reclassified out of accumulated other comprehensive income during the three or six months ended June 30, 2014.

| | Unrealized Gain (Loss) on Marketable Securities, net of tax | Foreign Currency Items (In thousands) | Total |
|---|--|---|----------|
| Balance at March 31, 2014 | \$ 83 | \$ 2,587 | \$ 2,670 |
| Other comprehensive income (loss) before reclassifications | 80 | (2) | 78 |
| Amounts reclassified from other comprehensive income | | | |
| Net current-period other comprehensive income | 80 | (2) | 78 |
| Balance at June 30, 2014 | \$ 163 | \$ 2,585 | \$ 2,748 |
| Balance at December 31, 2013 | \$ 82 | \$ 2,586 | \$ 2,668 |
| Other comprehensive income (loss) before reclassifications | 81 | (1) | 80 |
| Amounts reclassified from other comprehensive income | | | |
| Net current-period other comprehensive income | 81 | (1) | 80 |
| Balance at June 30, 2014 | \$ 163 | \$ 2,585 | \$ 2,748 |

(5) Fair Value Measurements

The following tables set forth the Company's financial assets subject to fair value measurements:

Edgar Filing: Celldex Therapeutics, Inc. - Form 10-Q

| | As of June 30, 2014 | Level 1 (In thousands) | Level 2 | Level 3 |
|---|------------------------|---------------------------|------------|---------|
| Money market funds and cash equivalents | \$ 30,885 | \$ | \$ 30,885 | \$ |
| Marketable securities | 211,572 | | 211,572 | |
| | \$ 242,457 | \$ | \$ 242,457 | \$ |

| | As of December 31, 2013 | Level 1 (In thousands) | Level 2 | Level 3 |
|---|----------------------------|---------------------------|------------|---------|
| Money market funds and cash equivalents | \$ 148,549 | \$ | \$ 148,549 | \$ |
| Marketable securities | 133,581 | | 133,581 | |
| | \$ 282,130 | \$ | \$ 282,130 | \$ |

There have been no transfers of assets or liabilities between the fair value measurement classifications. The Company's financial instruments consist mainly of cash and cash equivalents, marketable securities, short-term accounts receivable and accounts payable. The Company values its marketable securities utilizing independent pricing services which normally derive security prices from recently reported trades for identical or similar securities, making adjustments based on significant observable transactions. At

Table of Contents

each balance sheet date, observable market inputs may include trade information, broker or dealer quotes, bids, offers or a combination of these data sources. Short-term accounts receivable and accounts payable are reflected in the accompanying consolidated financial statements at cost, which approximates fair value due to the short-term nature of these instruments.

(6) Marketable Securities

A summary of marketable securities is shown below:

| | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
|---|-------------------|------------------------------|-------------------------------|------------|
| (In thousands) | | | | |
| June 30, 2014 | | | | |
| Marketable securities | | | | |
| U.S. government and municipal obligations | | | | |
| Maturing in one year or less | \$ 46,138 | \$ 59 | \$ | \$ 46,197 |
| Maturing after one year through three years | 39,447 | 89 | (11) | 39,525 |
| Total U.S. government and municipal obligations | \$ 85,585 | \$ 148 | \$ (11) | \$ 85,722 |
| Corporate debt securities | | | | |
| Maturing in one year or less | \$ 96,350 | \$ 39 | \$ (11) | \$ 96,378 |
| Maturing after one year through three years | 29,474 | 11 | (13) | 29,472 |
| Total corporate debt securities | \$ 125,824 | \$ 50 | \$ (24) | \$ 125,850 |
| Total marketable securities | \$ 211,409 | \$ 198 | \$ (35) | \$ 211,572 |
| December 31, 2013 | | | | |
| Marketable securities | | | | |
| U.S. government and municipal obligations | | | | |
| Maturing in one year or less | \$ 55,531 | \$ 27 | \$ (4) | \$ 55,554 |
| Maturing after one year through three years | 18,234 | 56 | (4) | 18,286 |
| Total U.S. government and municipal obligations | \$ 73,765 | \$ 83 | \$ (8) | \$ 73,840 |
| Corporate debt securities | | | | |
| Maturing in one year or less | \$ 38,973 | \$ 9 | \$ (9) | \$ 38,973 |
| Maturing after one year through three years | 20,761 | 12 | (5) | 20,768 |
| Total corporate debt securities | \$ 59,734 | \$ 21 | \$ (14) | \$ 59,741 |
| Total marketable securities | \$ 133,499 | \$ 104 | \$ (22) | \$ 133,581 |

The marketable securities held by the Company were high investment grade and there were no marketable securities that the Company considered to be other-than-temporarily impaired as of June 30, 2014. Marketable securities include \$1.7 million and \$0.9 million in accrued interest at June 30, 2014 and December 31, 2013, respectively.

(7) Intangible Assets and Goodwill

Edgar Filing: Celldex Therapeutics, Inc. - Form 10-Q

Intangible assets, net of accumulated amortization, and goodwill are as follows:

| | Estimated Life | Cost | June 30, 2014 Accumulated Amortization | Net (In thousands) | Cost | December 31, 2013 Accumulated Amortization | Net |
|----------------------------|-------------------|-----------|--|-----------------------|-----------|--|-----------|
| Intangible Assets: | | | | | | | |
| IPR&D | Indefinite | \$ 11,800 | \$ | \$ 11,800 | \$ 11,800 | \$ | \$ 11,800 |
| Amgen Amendment | 16 years | 14,500 | (4,260) | 10,240 | 14,500 | (3,812) | 10,688 |
| Core Technology | 11 years | 1,296 | (1,023) | 273 | 1,296 | (964) | 332 |
| Total Intangible Assets | | \$ 27,596 | \$ (5,283) | \$ 22,313 | \$ 27,596 | \$ (4,776) | \$ 22,820 |
| Goodwill | Indefinite | \$ 8,965 | \$ | \$ 8,965 | \$ 8,965 | \$ | \$ 8,965 |

The IPR&D intangible asset was recorded in connection with the acquisition of CuraGen and relates to the development of glembatumumab vedotin. At the date of acquisition and at June 30, 2014, glembatumumab vedotin had not yet reached technological feasibility nor did it have any alternative future use. Glembatumumab vedotin is in a randomized study for the treatment of triple negative breast cancer designed to obtain accelerated approval.

Table of Contents**(8) Other Long-Term Liabilities**

Other long-term liabilities include the following:

| | June 30, 2014 | December 31, 2013 |
|---|----------------|-------------------|
| | (In thousands) | |
| Deferred Rent | \$ 518 | \$ 419 |
| Net Deferred Tax Liability related to IPR&D | 4,661 | 4,661 |
| Deferred Income from Sale of Tax Benefits | 2,252 | 1,630 |
| Deferred Revenue | 5,762 | 1,168 |
| Total | 13,193 | 7,878 |
| Less Current Portion | (2,118) | (928) |
| Long-Term Portion | \$ 11,075 | \$ 6,950 |

In January 2014, 2013, 2012 and 2011, the Company received approval from the New Jersey Economic Development Authority and agreed to sell New Jersey tax benefits worth \$1.1 million, \$0.8 million, \$0.8 million and \$0.6 million to an independent third party for \$1.0 million, \$0.8 million, \$0.7 million and \$0.5 million, respectively. Under the agreement, the Company must maintain a base of operations in New Jersey for five years or the tax benefits must be paid back on a pro-rata basis based on the number of years completed. During the six months ended June 30, 2014 and 2013, the Company recorded \$0.4 million and \$0.2 million to other income related to the sale of these tax benefits, respectively.

In September 2013, the Company entered into an agreement with Rockefeller University pursuant to which the Company will perform research and development services for Rockefeller. The agreement includes an approved project plan for the development services of \$4.8 million and a term of three years. The agreement included an upfront payment of \$1.3 million which is being recognized as revenue over the term of the agreement. The Company will bill Rockefeller quarterly for actual time and direct costs incurred and record those amounts to revenue in the quarter the services are performed. The Company recorded \$0.4 million and \$0.7 million in revenue related to the Rockefeller agreement during the three and six months ended June 30, 2014.

In May 2014, the Company entered into a clinical trial collaboration with Bristol-Myers Squibb Company (BMS) to evaluate the safety, tolerability and preliminary efficacy of varlilumab and nivolumab, BMS's PD-1 immune checkpoint inhibitor, in a Phase 1/2 study. Under the terms of this clinical trial collaboration, BMS made a one-time payment to the Company of \$5.0 million and the companies amended the terms of the Company's existing license agreement with Medarex (a subsidiary of BMS) related to the Company's CD27 program whereby certain future milestone payments were waived and future royalty rates were reduced that may have been due from the Company to Medarex. In return, BMS was granted a time-limited right of first negotiation if the Company wishes to out-license varlilumab. The companies also agreed to work exclusively with each other to explore anti-PD-1 antagonist antibody and anti-CD27 agonist antibody combination regimens. The clinical trial collaboration provides that the companies will share development costs and that the Company will be responsible for conducting the Phase 1/2 study, which is expected to begin in the fourth quarter of 2014.

The Company has determined that its performance obligations under the BMS agreement, which primarily include performing research and development, supplying varlilumab and participating in the joint development committee, should be accounted for as a single unit of accounting and estimated that its performance period under the BMS agreement would be 5 years. Accordingly, the \$5 million up-front payment was initially recorded as deferred revenue and is being recognized as revenue on a straight-line basis over the estimated 5-year performance period using the Contingency Adjusted Performance Model (CAPM). The BMS agreement also provides for BMS to reimburse the Company for 50%

Edgar Filing: Celldex Therapeutics, Inc. - Form 10-Q

of the external costs incurred by the Company in connection with the clinical trial. These BMS payments will be recognized as revenue under the CAPM. The Company recorded \$0.2 million in revenue related to the BMS agreement during the three months ended June 30, 2014.

(9) Stockholders' Equity

During the six months ended June 30, 2013, the Company issued 2,433,608 shares of its common stock under its controlled equity offering sales agreement with Cantor Fitzgerald & Co., as amended, resulting in net proceeds to the Company of \$17.1 million, after deducting commission and offering expenses.

During the six months ended June 30, 2013, the Company issued 13,800,000 shares of its common stock in an underwritten public offering resulting in net proceeds to the Company of \$97.0 million, after deducting underwriting fees and offering expenses.

Table of Contents
(10) Stock-Based Compensation

A summary of stock option activity for the six months ended June 30, 2014 is as follows:

| | Shares | Weighted Average Exercise Price Per Share | Weighted Average Remaining Contractual Term (In Years) |
|--|-----------|---|--|
| Options Outstanding at December 31, 2013 | 5,770,544 | \$ 8.17 | 7.0 |
| Granted | 1,333,850 | \$ 13.57 | |
| Exercised | (134,131) | \$ 6.05 | |
| Canceled | (8,497) | \$ 10.51 | |
| Options Outstanding at June 30, 2014 | 6,961,766 | \$ 9.24 | 7.2 |
| Options Vested and Expected to Vest at June 30, 2014 | 6,886,817 | \$ 9.19 | 7.2 |
| Options Exercisable at June 30, 2014 | 3,480,200 | \$ 6.18 | 5.3 |
| Shares Available for Grant under the 2008 Plan | 765,589 | | |

The weighted average grant-date fair value of stock options granted during the six months ended June 30, 2014 was \$8.76. Stock-based compensation expense for the three and six months ended June 30, 2014 and 2013 was recorded as follows:

| | Three months ended June 30, | | Six months ended June 30, | |
|--|-----------------------------|--------|---------------------------|----------|
| | 2014 | 2013 | 2014 | 2013 |
| | (In thousands) | | | |
| Research and development | \$ 747 | \$ 422 | \$ 1,338 | \$ 863 |
| General and administrative | 764 | 254 | 1,423 | 521 |
| Total stock-based compensation expense | \$ 1,511 | \$ 676 | \$ 2,761 | \$ 1,384 |

The fair values of employee and director stock options granted during the three and six months ended June 30, 2014 and 2013 were valued using the Black-Scholes option-pricing model with the following assumptions:

| | Three months ended June 30, | | Six months ended June 30, | |
|---------------------------------|-----------------------------|------------|---------------------------|------------|
| | 2014 | 2013 | 2014 | 2013 |
| Expected stock price volatility | 72% | 72% | 71 - 72% | 72% |
| Expected option term | 6.0 years | 6.0 years | 6.0 years | 6.0 years |
| Risk-free interest rate | 2.2% | 1.2 - 1.8% | 2.2% | 1.2 - 1.8% |
| Expected dividend yield | None | None | None | None |

(11) Income Taxes

Massachusetts, New Jersey and Connecticut are the three states in which the Company primarily operates or has operated and has income tax nexus. The Company is not currently under examination by any jurisdictions for any tax year.

The Company has evaluated the positive and negative evidence bearing upon the realizability of its net deferred tax assets, which are comprised principally of net operating loss carryforwards, capitalized R&D expenditures and R&D tax credit carryforwards. The Company has determined that it is more likely than not that it will not recognize the benefits of federal and state deferred tax assets and, as a result, a full valuation allowance was maintained at June 30, 2014 and December 31, 2013 against the Company's net deferred tax assets.

Table of Contents

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

Safe Harbor Statement under the Private Securities Litigation Reform Act of 1995: This report on Form 10-Q contains forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 under Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements include statements with respect to our beliefs, plans, objectives, goals, expectations, anticipations, assumptions, estimates, intentions and future performance, and involve known and unknown risks, uncertainties and other factors, which may be beyond our control, and which may cause our actual results, performance or achievements to be materially different from future results, performance or achievements expressed or implied by such forward-looking statements. All statements other than statements of historical fact are statements that could be forward-looking statements. You can identify these forward-looking statements through our use of words such as may, will, can, anticipate, assume, should, indicate, would, believe, contemplate, expect, seek, estimate, continue, plan, point to, project, predict, could, intend, and similar words and expressions of the future.

There are a number of important factors that could cause the actual results to differ materially from those expressed in any forward-looking statement made by us. These factors include, but are not limited to:

- our ability to successfully complete research and further development, including animal, preclinical and clinical studies, and, if we obtain regulatory approval, commercialization of rindopepimut (also referred to as CDX-110), glembatumumab vedotin (also referred to as CDX-011), and other drug candidates and the growth of the markets for those drug candidates;
- our ability to raise sufficient capital to fund our clinical studies and to meet our long-term liquidity needs, on terms acceptable to us, or at all. If we are unable to raise the funds necessary to meet our long-term liquidity needs, we may have to delay or discontinue the development of one or more programs, discontinue or delay on-going or anticipated clinical trials, license out programs earlier than expected, raise funds at significant discount or on other unfavorable terms, if at all, or sell all or part of our business;
- our ability to manage multiple clinical trials for a variety of drug candidates at different stages of development, including ACT IV and ReACT for rindopepimut and METRIC for glembatumumab vedotin;
- the cost, timing, scope and results of ongoing safety and efficacy trials of rindopepimut, glembatumumab vedotin, and other preclinical and clinical testing;
- our ability to fund and complete the development and, if we obtain regulatory approval, to commercialize rindopepimut in North America ourselves;
- our ability to negotiate strategic partnerships, where appropriate, for our programs, which may include rindopepimut outside of North America, glembatumumab vedotin and varlilumab (also referred to as CDX-1127);

Edgar Filing: Celldex Therapeutics, Inc. - Form 10-Q

- our ability to develop technological capabilities, including identification of novel and clinically important targets, exploiting our existing technology platforms to develop new product candidates and expand our focus to broader markets for our existing targeted immunotherapeutics;
- our ability to adapt our proprietary antibody-targeted technology, or APC Targeting Technology , to develop new, safe and effective therapeutics for oncology and infectious disease indications;
- the availability, cost, delivery and quality of clinical and commercial grade materials produced by our own manufacturing facility or supplied by contract manufacturers, suppliers and partners, who may be the sole source of supply;
- the availability, cost, delivery and quality of clinical management services provided by our clinical research organization partners;
- the timing, cost and uncertainty of obtaining regulatory approvals for our drug candidates;
- our ability to develop and commercialize products before competitors that are superior to the alternatives developed by such competitors;

Table of Contents

- our ability to protect our intellectual property rights and our ability to avoid intellectual property litigation, which can be costly and divert management time and attention; and
- the factors listed under the headings Business, Risk Factors and Management's Discussion and Analysis of Financial Condition and Results of Operations in the Company's annual report on Form 10-K for the year ended December 31, 2013 and other reports that we file with the Securities and Exchange Commission.

All forward-looking statements are expressly qualified in their entirety by this cautionary notice. You are cautioned not to place undue reliance on any forward-looking statements, which speak only as of the date of this report or the date of the document incorporated by reference into this report. We have no obligation, and expressly disclaim any obligation, to update, revise or correct any of the forward-looking statements, whether as a result of new information, future events or otherwise. We have expressed our expectations, beliefs and projections in good faith and we believe they have a reasonable basis. However, we cannot assure you that our expectations, beliefs or projections will result or be achieved or accomplished.

OVERVIEW

We are a biopharmaceutical company focused on the development and commercialization of several immunotherapy technologies for the treatment of cancer and other difficult-to-treat diseases. Our drug candidates are derived from a broad set of complementary technologies which have the ability to utilize the human immune system and enable the creation of therapeutic agents. We are using these technologies to develop targeted immunotherapeutics comprised of antibodies, adjuvants and monotherapies and antibody-drug conjugates that prevent or treat cancer and other diseases that modify undesirable activity by the body's own proteins or cells.

Our lead drug candidates include rindopepimut (also referred to as CDX-110) and glembatumumab vedotin (also referred to as CDX-011). Rindopepimut is a targeted immunotherapeutic in a pivotal Phase 3 study for the treatment of front-line glioblastoma and a Phase 2 study for the treatment of recurrent glioblastoma. Glembatumumab vedotin is a targeted antibody-drug conjugate in a randomized study for the treatment of triple negative breast cancer designed to obtain accelerated approval. We also have a number of earlier stage drug candidates in clinical development, including varlilumab (also referred to as CDX-1127), a fully human therapeutic monoclonal antibody for cancer indications, CDX-301, an immune cell mobilizing agent and dendritic cell growth factor and CDX-1401, a targeted immunotherapeutic aimed at antigen presenting cells, or APC, for cancer indications. Our drug candidates address market opportunities for which we believe current therapies are inadequate or non-existent.

We are building a fully integrated, commercial-stage biopharmaceutical company that develops important therapies for patients with unmet medical needs. Our program assets provide us with the strategic options to either retain full economic rights to our innovative therapies or seek favorable economic terms through advantageous commercial partnerships. This approach allows us to maximize the overall value of our technology and product portfolio while best ensuring the expeditious development of each individual product.

The following table includes the programs that we currently believe are significant to our business:

Edgar Filing: Celldex Therapeutics, Inc. - Form 10-Q

| Product (generic) | Indication/Field | Partner | Status |
|-----------------------|---|---------|-------------|
| CLINICAL | | | |
| Rindopepimut | Front-line glioblastoma | | Phase 3 |
| Glembatumumab vedotin | Metastatic breast cancer and melanoma | | Phase 2b |
| Rindopepimut | Recurrent glioblastoma | | Phase 2 |
| Varlilumab | Lymphoma/leukemia and solid tumors | | Phase 1 |
| CDX-1401 | Multiple solid tumors | | Phase 1 |
| CDX-301 | Cancer, autoimmune disease and transplant | | Phase 1 |
| PRECLINICAL | | | |
| CDX-014 | Ovarian and renal cancer | | Preclinical |

The expenditures that will be necessary to execute our business plan are subject to numerous uncertainties. Completion of clinical trials may take several years or more, and the length of time generally varies substantially according to the type, complexity, novelty and intended use of a product candidate. It is not unusual for the clinical development of these types of product candidates to each take five years or more, and for total development costs to exceed \$100 million for each product candidate. We estimate that clinical trials of the type we generally conduct are typically completed over the following timelines:

Table of Contents

| Clinical Phase | Estimated Completion Period |
|----------------|-----------------------------|
| Phase 1 | 1 - 2 Years |
| Phase 2 | 1 - 5 Years |
| Phase 3 | 1 - 5 Years |

The duration and the cost of clinical trials may vary significantly over the life of a project as a result of differences arising during the clinical trial protocol, including, among others, the following:

- the number of patients that ultimately participate in the trial;
- the duration of patient follow-up that seems appropriate in view of results;
- the number of clinical sites included in the trials;
- the length of time required to enroll suitable patient subjects; and
- the efficacy and safety profile of the product candidate.

We test potential product candidates in numerous preclinical studies for safety, toxicology and immunogenicity. We may then conduct multiple clinical trials for each product candidate. As we obtain results from trials, we may elect to discontinue or delay clinical trials for certain product candidates in order to focus our resources on more promising product candidates.

An element of our business strategy is to pursue the research and development of a broad portfolio of product candidates. This is intended to allow us to diversify the risks associated with our research and development expenditures. As a result, we believe our future capital requirements and our future financial success are not substantially dependent on any one product candidate. To the extent we are unable to maintain a broad range of product candidates, our dependence on the success of one or a few product candidates increases.

Regulatory approval is required before we can market our product candidates as therapeutic products. In order to proceed to subsequent clinical trial stages and to ultimately achieve regulatory approval, the regulatory agency must conclude that our clinical data is safe and effective. Historically, the results from preclinical testing and early clinical trials (through Phase 2) have often not been predictive of results obtained in later clinical trials. A number of new drugs and biologics have shown promising results in early clinical trials, but subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals.

Furthermore, our business strategy includes the option of entering into collaborative arrangements with third parties to complete the development and commercialization of our product candidates. In the event that third parties take over the clinical trial process for one of our product candidates, the estimated completion date would largely be under control of that third party rather than us. We cannot forecast with any degree of certainty which proprietary products, if any, will be subject to future collaborative arrangements, in whole or in part, and how such arrangements would affect our development plan or capital requirements. Our programs may also benefit from subsidies, grants, contracts or government or agency-sponsored studies that could reduce our development costs.

As a result of the uncertainties discussed above, among others, it is difficult to accurately estimate the duration and completion costs of our research and development projects or when, if ever, and to what extent we will receive cash inflows from the commercialization and sale of a product. Our inability to complete our research and development projects in a timely manner or our failure to enter into collaborative agreements, when appropriate, could significantly increase our capital requirements and could adversely impact our liquidity. These uncertainties could force us to seek additional, external sources of financing from time to time in order to continue with our business strategy. Our inability to raise additional capital, or to do so on terms reasonably acceptable to us, would jeopardize the future success of our business.

During the past five years through December 31, 2013, we incurred an aggregate of \$201.1 million in research and development expenses. The following table indicates the amount incurred for each of our significant research programs and for other identified research and development activities during the six months ended June 30, 2014 and 2013. The amounts disclosed in the following table reflect direct research and development costs, license fees associated with the underlying technology and an allocation of indirect research and development costs to each program.

Table of Contents

| | Six Months Ended June 30, | |
|-----------------------|---------------------------|-----------|
| | 2014 | 2013 |
| | (In thousands) | |
| Rindopepimut | \$ 25,917 | \$ 17,743 |
| Glembatumumab vedotin | 14,799 | 2,778 |
| Varlilumab | 4,433 | 4,524 |
| CDX-1401 | 2,058 | 318 |
| CDX-301 | 581 | 260 |
| CDX-014 | 1,815 | 508 |
| Other Programs | 1,566 | 3,049 |
| Total R&D Expense | \$ 51,169 | \$ 29,180 |

Clinical Development Programs*Rindopepimut*

Rindopepimut is an immunotherapeutic that targets the tumor-specific molecule epidermal growth factor receptor variant III, or EGFRvIII. EGFRvIII is a mutated form of the epidermal growth factor receptor, or EGFR, that is only expressed in cancer cells and not in normal tissue and can directly contribute to cancer cell growth. EGFRvIII is expressed in approximately 30% of glioblastoma multiforme, or GBM, tumors, the most common and aggressive form of brain cancer. Rindopepimut is composed of the EGFRvIII peptide linked to a carrier protein called Keyhole Limpet Hemocyanin, or KLH, and administered together with the adjuvant GM-CSF. The Food and Drug Administration, or FDA, and the European Medicines Agency, or EMA, have both granted orphan drug designation for rindopepimut for the treatment of EGFRvIII expressing GBM. The FDA has also granted Fast Track designation.

The Phase 2a study of rindopepimut referred to as ACTIVATE was led by collaborating investigators at the Brain Center at Duke Comprehensive Cancer Center in Durham, North Carolina and at M.D. Anderson Cancer Center in Houston, Texas and enrolled 18 evaluable GBM patients. An extension of the Phase 2a study referred to as ACT II evaluated 22 additional GBM patients treated in combination with the current standard of care, maintenance temozolomide, or TMZ, at the same two institutions.

The Phase 2b study of rindopepimut referred to as ACT III combined rindopepimut with standard of care, TMZ, in patients with newly diagnosed GBM. The ACT III study provided for a multi-center, non-randomized dataset for rindopepimut in 65 patients at over 30 sites throughout the United States.

In November 2013, we announced the four- and five-year survival data from the 105 patients enrolled in the three Phase 2 rindopepimut clinical studies (ACTIVATE, ACT II and ACT III) in EGFRvIII-positive GBM. Across these three Phase 2 studies of rindopepimut, survival data remains consistent and suggests a continuing survival benefit in comparison to independent control datasets (see chart below) at the median and at all other time points evaluated.

Phase 2 Frontline Long-term Overall Survival Assessments

Edgar Filing: Celldex Therapeutics, Inc. - Form 10-Q

| | Median, Years (95% CI) | 2-year rate | 3-year rate | 4-year rate | 5-year rate |
|--------------------------------------|---------------------------|----------------|----------------|----------------|----------------|
| Phase 2 rindopepimut studies (n=105) | 2.1 (1.8, 2.4) | 51% | 30% | 18% | 14% |
| Matched historical control (n=17)(1) | 1.3 (0.9, 1.7) | 6% | 6% | 0% | 0% |

(1) *Patients treated at M.D. Anderson contemporaneously to ACTIVATE, matched for major eligibility requirements, including EGFRvIII-positive GBM, gross total resection and no disease progression through chemoradiation treatment.*

The pooled overall long-term survival results continue to be consistent with the ACT III Phase 2 study (18% for 4-years and 14% for 5-years).

In December 2011, we initiated ACT IV, a pivotal, randomized, double-blind, controlled Phase 3 study of rindopepimut in patients with surgically resected, EGFRvIII-positive GBM. Patients are randomized after the completion of surgery and standard chemoradiation treatment. The treatment regimen includes a rindopepimut priming phase post-radiation followed by an adjuvant TMZ phase and a rindopepimut maintenance therapy phase. Patients are treated until disease progression or intolerance to therapy. The primary objective of the study is to determine whether rindopepimut plus adjuvant GM-CSF improves the overall survival of patients with newly diagnosed EGFRvIII-positive GBM after Gross Total Resection, or GTR, when compared to treatment with TMZ and a control injection of KLH. KLH is a component of rindopepimut and was selected due to its ability to generate a similar injection site reaction to that observed with rindopepimut. ACT IV is enrolling patients at over 200 centers worldwide and is expected to accrue 700

Table of Contents

patients to reach the required 374 patients with minimal residual disease needed for analysis of the primary endpoint, overall survival. All patients, including patients with disease that exceed this threshold will be included in the analysis of secondary endpoints including progression-free survival, safety and tolerability, neurologic status and quality of life. Based on current projections, we anticipate that we will close screening in the third quarter of 2014 and that the last patient will be randomized into the study in the fourth quarter of 2014.

In December 2011, we also initiated ReACT, a Phase 2 study of rindopepimut in combination with Avastin® in patients with recurrent EGFRvIII-positive GBM. ReACT was initially planned to enroll approximately 95 patients in a first or second relapse of GBM following receipt of standard therapy at approximately 25 sites across the United States. In August 2013, we announced the addition of an expansion cohort of approximately 75 patients (Group 2C) to better characterize the potential activity of rindopepimut in this refractory patient population. This decision was based on early evidence of anti-tumor activity, including stable disease, tumor shrinkage and investigator-reported response. As amended, the ReACT study will now enroll approximately 170 patients across three groups. Approximately 70 patients (Group 1) who have yet to receive Avastin will be randomized to receive either rindopepimut and Avastin or a control injection of KLH and Avastin in a blinded fashion. Another 100 patients, including the expansion cohort of 75 patients, who are refractory to Avastin having received Avastin in either the frontline or recurrent setting with subsequent progression will receive rindopepimut plus Avastin in a single treatment arm. Study endpoints include 6 month progression free survival rate, objective response rate, or ORR, overall survival and safety and tolerability.

In November 2013, we reported interim data from our ongoing Phase 2 ReACT study. Rindopepimut plus Avastin was very well tolerated (dosing up to 13+ months) and the results demonstrated promising signs of clinical activity in advanced patient populations, including evidence of anti-tumor activity (tumor shrinkage, objective response and stable disease). Strong immune response correlated with improved outcome. In Avastin-naïve patients treated with both rindopepimut and Avastin, a strong survival trend has also been seen to date versus the control group (see chart below).

Interim ReACT Overall Survival and Progression-free Survival in Avastin-Naïve Recurrent GBM

| | Rindopepimut & Avastin (n=20) | Control & Avastin (n=20) | Hazard Ratio |
|---------------------------|----------------------------------|-----------------------------|-------------------|
| Overall survival | 12.0 months | 7.9 months p=0.16 | 0.43 (0.13, 1.44) |
| Progression-free survival | 3.7 months | 2.0 months P=0.47 | 0.74 (0.34, 1.61) |

In Avastin-refractory patients treated with both rindopepimut and Avastin, a median progression-free survival, or PFS, of 1.9 months and an overall survival, or OS, of 5.6 months was observed. The median overall survival of 5.6 months is noteworthy in these heavily pre-treated, refractory EGFRvIII-positive patients. A review of the literature assessing survival in recurrent patients who are Avastin-experienced across eight independent studies suggests a weighted-average survival of 3.6 months (range of 2.6 to 5.8 months) in all-comers. It is important to note that these eight studies do not necessarily meet the strict definition of refractory applied in the ReACT study and that these studies included EGFRvIII-negative patients who tend to perform better. Progression-free survival results in this refractory population may be more consistent with the profile of an immunotherapy candidate where progression-free survival does not always correlate directly with an overall survival benefit.

Edgar Filing: Celldex Therapeutics, Inc. - Form 10-Q

Enrollment to Group 1 (Avastin-naïve patients) and enrollment of the first 23 patients in Group 2C (Avastin-refractory patients) is complete. Group 2C is designed as a two-stage cohort; evidence of anti-tumor activity in the first 23 patients will trigger full completion of enrollment to this arm of the study. Updated data from the study will be presented by year-end 2014.

Glebatumumab Vedotin

Glebatumumab vedotin is an antibody-drug conjugate, or ADC, that consists of a fully-human monoclonal antibody, CR011, linked to a potent cell-killing drug, monomethyl-auristatin E, or MMAE. The CR011 antibody specifically targets glycoprotein NMB, referred to as gpNMB, that is over-expressed in a variety of cancers including breast cancer and melanoma. The ADC technology, comprised of MMAE and a stable linker system for attaching it to CR011, was licensed from Seattle Genetics, Inc. and is the same as that used in the marketed product Adcetris®. The ADC is designed to be stable in the bloodstream. Following intravenous administration, glebatumumab vedotin targets and binds to gpNMB and upon internalization into the targeted cell, glebatumumab vedotin is designed to release MMAE from CR011 to produce a cell-killing effect. The FDA has granted Fast Track designation to glebatumumab vedotin for the treatment of advanced, refractory/resistant gpNMB-expressing breast cancer.

Table of Contents

Treatment of Breast Cancer: The Phase 1/2 study of glembatumumab vedotin administered intravenously once every three weeks evaluated patients with locally advanced or metastatic breast cancer who had received prior therapy (median of seven prior regimens). The study began with a bridging phase to confirm the maximum tolerated dose, or MTD, and then expanded into a Phase 2 open-label, multi-center study. The study confirmed the safety of glembatumumab vedotin at the pre-defined maximum dose level (1.88 mg/kg) in 6 patients. An additional 28 patients were enrolled in an expanded Phase 2 cohort (for a total of 34 treated patients at 1.88 mg/kg, the Phase 2 dose) to evaluate the PFS rate at 12 weeks. The 1.88 mg/kg dose was well tolerated in this patient population with the most common adverse events of rash, alopecia, and fatigue. The primary activity endpoint, which called for at least 5 of 25 (20%) patients in the Phase 2 study portion to be progression-free at 12 weeks, was met as 9 of 26 (35%) evaluable patients were progression-free at 12 weeks.

For all patients treated at the maximum dose level, tumor shrinkage was seen in 62% (16/26) and median PFS was 9.1 weeks. A subset of 10 patients had triple negative disease, a more aggressive breast cancer subtype that carries a high risk of relapse and reduced survival as well as limited therapeutic options due to lack of over-expression of HER2/neu, estrogen and progesterone receptors. In these patients, 78% (7/9) had some tumor shrinkage, 12-week PFS rate was 70% (7/10), and median PFS was 17.9 weeks. Tumor samples from a subset of patients across all dose groups were analyzed for gpNMB expression. The tumor samples from most patients showed evidence of stromal and/or tumor cell expression of gpNMB.

In December 2012, we announced final results from the EMERGE study, a randomized, multi-center Phase 2b study of glembatumumab vedotin in 122 patients with heavily pre-treated, advanced, gpNMB positive breast cancer. Patients were randomized (2:1) to receive either glembatumumab vedotin or single-agent Investigator's Choice, or IC, chemotherapy. Patients randomized to receive IC were allowed to cross over to receive glembatumumab vedotin following disease progression. Activity endpoints included response rate, PFS and OS. The final results, as shown below, suggested that glembatumumab vedotin induces significant response rates compared to currently available therapies in patient subsets with advanced, refractory breast cancers with gpNMB over-expression (expression in greater than 25% of tumor cells) and in patients with triple negative breast cancer. The OS and PFS of patients treated with glembatumumab vedotin was also observed to be greatest in patients with triple negative breast cancer who also over-express gpNMB and all patients with gpNMB over-expression.

EMERGE: Overall Response Rate and Disease Control Data

| | gpNMB Over-Expression | | Triple Negative and gpNMB Over-Expression | |
|----------------------|------------------------------|---------------------------|---|---------------------------|
| | glembatumumab vedotin (n=25) | Investigator Choice (n=8) | glembatumumab vedotin (n=12) | Investigator Choice (n=4) |
| Response | 32% | 13% | 33% | 0% |
| Disease Control Rate | 64% | 38% | 75% | 25% |

Responses per RECIST 1.1; IC = Investigator's Choice; glembatumumab vedotin arm includes 15 patients who crossed over to receive glembatumumab vedotin treatment after progression on IC. Analysis of best response excludes patients who discontinued from study without evaluable post-baseline radiographic imaging (n=15 for glembatumumab vedotin arm; n=5 for IC arm).

EMERGE: Progression Free Survival (PFS) and Overall Survival (OS) Data

Edgar Filing: Celldex Therapeutics, Inc. - Form 10-Q

| | gpNMB Over-Expression | | Triple Negative and gpNMB Over-Expression | |
|---------------------|--------------------------|------------------------|---|------------------------|
| | glembatumumab vedotin | Investigator Choice | glembatumumab vedotin | Investigator Choice |
| Median PFS (months) | 2.7 | 1.5 | 3.0 | 1.5 |
| | p=0.14 | | p=0.008 | |
| Median OS (months) | 10.0 | 5.7 | 10.0 | 5.5 |
| | p=0.18 | | p=0.003 | |

When cross over patients are removed, median OS in patients with gpNMB over-expression is 10.0 months for glembatumumab vedotin vs 5.2 months for IC (p=0.05) and median OS in triple negative patients with gpNMB over- expression is 10.0 months for glembatumumab vedotin vs 5.2 months for IC (p=0.009).

Table of Contents

In December 2013, we initiated METRIC, a randomized, controlled study of glembatumumab vedotin in patients with triple negative breast cancer that over-express gpNMB designed to obtain accelerated approval. METRIC will be conducted in approximately 100 sites, primarily across the United States with additional sites in Canada and Australia and will enroll approximately 300 patients.

Treatment of Metastatic Melanoma: The Phase 1/2 open-label, multi-center, dose escalation study evaluated the safety, tolerability and pharmacokinetics of glembatumumab vedotin in 117 patients with un-resectable Stage III or Stage IV melanoma who had failed no more than one prior line of cytotoxic therapy. The MTD was determined to be 1.88 mg/kg administered intravenously once every three weeks. The study achieved its primary activity objective with an ORR in the Phase 2 cohort of 15% (5/34). Median PFS was 3.9 months. Glembatumumab vedotin was generally well tolerated, with the most frequent treatment-related adverse events being rash, fatigue, hair loss, pruritus, diarrhea and neuropathy. In the subset of patients with tumor biopsies, high levels of tumor expression of gpNMB appeared to correlate with favorable outcome. In the seven patients whose tumors were found to express high amounts of gpNMB, and who were treated at the maximum tolerated doses across all dosing schedules, median PFS was 4.9 months. The development of rash, which may be associated with the presence of gpNMB in the skin also seemed to correlate with greater PFS.

The Company is currently exploring conducting additional clinical studies in indications known to express gpNMB. A Phase 2 study in metastatic melanoma is expected to be initiated in the second half of 2014. Assay optimization and validation for a Phase 2 study in squamous cell lung cancer is expected to be completed by year-end and the study will commence soon after. We have also entered into a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute under which we will collaborate initially on two studies of glembatumumab vedotin one in uveal melanoma and one in pediatric osteosarcoma.

Varlilumab

Varlilumab is a human monoclonal antibody that targets CD27, a potentially important target for immunotherapy of various cancers. We have entered into license agreements with the University of Southampton, UK for intellectual property related to uses of anti-CD27 antibodies and with Medarex (now a subsidiary of the Bristol-Myers Squibb Company, or BMS) for access to the UltiMab technology to develop and commercialize human antibodies to CD27. In July 2013, the United States Patent and Trademark Office issued a patent to the University of Southampton, that we have exclusive license to under our license agreement, which broadly supports varlilumab. The patent includes 18 claims covering various methods of treating cancer using agonistic anti-human CD27 antibodies and relates, among other things, directly to our CD27 antibody program and therapeutic uses of varlilumab.

CD27 acts downstream from CD40 and may provide a novel way to regulate the immune responses. CD27 is a co-stimulatory molecule on T cells and is over-expressed in certain lymphomas and leukemias. Varlilumab is an agonist antibody designed to have two potential therapeutic mechanisms. Varlilumab has been shown to activate immune cells that can target and eliminate cancerous cells in tumor-bearing mice and to directly kill or inhibit the growth of CD27 expressing lymphomas and leukemias *in vitro* and *in vivo*. Both mechanisms have been seen even at low doses in appropriate preclinical models.

We are conducting an open label Phase 1 study of varlilumab in patients with selected malignant solid tumors or hematologic cancers at multiple clinical sites in the United States. Initial dose escalation cohorts were conducted to determine an optimal dose for future study and, to date, no maximum tolerated dose has been reached. The lymphoid malignancies dose escalation arm has completed enrollment (n=24) and a new cohort has been added to include evaluation of T cell malignancies. The solid tumor arm, which included patients with various solid tumors, completed dose escalation in 2013. Two expansion cohorts were subsequently added at 3 mg/kg dosed weekly in metastatic melanoma (n=16) and renal cell carcinoma (n=15) to better characterize clinical activity and further define the safety profile in preparation for combination studies.

We presented data from this Phase 1 study in June 2014. Varlilumab was very well tolerated and induced immunologic activity in patients that is consistent with both its mechanism of action and preclinical models. In the lymphoid malignancies dose escalation arm (n=24) two patients were continuing treatment and had not yet been evaluated for response. A heavily pre-treated patient with aggressive Hodgkin lymphoma had achieved a complete response. She continued in remission at 12.9+ months. Six additional patients with Hodgkin lymphoma had been enrolled, with one patient awaiting initial response evaluation. Three additional patients with non-Hodgkin lymphoma had experienced stable disease with a PFS range of 4.5 to 14 months. One of these patients experienced significant tumor shrinkage (36%). All patients had completed treatment in the solid tumor dose escalation arm (n=25). Four patients experienced stable disease (SD) with a PFS range of 3.0 to 22.4+ months. In the melanoma cohort, three patients had ongoing SD with a PFS range of 2.7+ to 11.5+ months, including a uveal melanoma patient with 12% shrinkage of measurable disease. In the renal cell carcinoma expansion cohort, one patient achieved a partial response at 2.7+ months. Additionally, three patients had SD with a duration of 2.8+ to 8.4+ months. Five patients continued on treatment, one of whom had not yet been seen for the first assessment of response. Based on these data, we intend to initiate new studies of varlilumab in combination with various agents in the second half of 2014.

Table of Contents

In May 2014, we entered into a clinical trial collaboration with BMS to evaluate the safety, tolerability and preliminary efficacy of varlilumab and nivolumab, BMS's PD-1 immune checkpoint inhibitor, in a Phase 1/2 study. Multiple tumor types will be explored in the study, which could potentially include non-small cell lung cancer (NSCLC), metastatic melanoma, ovarian, colorectal (CRC) and squamous cell head and neck cancers. The Phase 1/2 study is expected to begin in the fourth quarter of 2014.

CDX-1401

CDX-1401, developed from our APC Targeting Technology, is a fusion protein consisting of a fully human monoclonal antibody with specificity for the dendritic cell receptor, DEC-205, linked to the NY-ESO-1 tumor antigen. In humans, NY-ESO-1 has been detected in 20 - 30% of all melanoma, lung, esophageal, liver, gastric, prostate, ovarian and bladder cancers, thus representing a broad opportunity. This product is intended to selectively deliver the NY-ESO-1 antigen to dendritic cells for generating robust immune responses against cancer cells expressing NY-ESO-1. We are developing CDX-1401 for the treatment of malignant melanoma and a variety of solid tumors which express the proprietary cancer antigen NY-ESO-1, which we licensed from the Ludwig Institute for Cancer Research in 2006. Preclinical studies have shown that CDX-1401 is effective for activation of human T cell responses against NY-ESO-1.

The Phase 1 study assessed the safety, immunogenicity and clinical activity of escalating doses of CDX-1401 with TLR agonists (resiquimod and/or Poly ICLC) in 45 patients with advanced malignancies refractory to all available therapies. 60% of patients had confirmed NY-ESO expression in archived tumor sample. Thirteen patients maintained stable disease for up to 13.4 months with a median of 6.7 months. Treatment was well-tolerated and there were no dose limiting toxicities. Humoral responses were elicited in both NY-ESO-1 positive and negative patients. NY-ESO-1-specific T cell responses were absent or low at baseline, but increased post-vaccination in 53% of evaluable patients, including both CD4 and/or CD8 T cell responses. Robust immune responses were observed with CDX-1401 with resiquimod and Poly ICLC alone and in combination. Long-term patient follow up suggested that treatment with CDX-1401 may predispose patients to better outcomes on subsequent therapy with checkpoint inhibitors. Of the 45 patients in the Phase 1 study, eight went on to receive subsequent therapy of either ipilimumab or an investigational checkpoint inhibitor and six of these patients had objective tumor regression. Six patients with melanoma received ipilimumab within three months of treatment with CDX-1401 and four (67%) had objective tumor responses, including one complete response, which compares favorably to the overall response rate of 11% previously reported in metastatic melanoma patients treated with single-agent ipilimumab. In addition, two patients with non-small cell lung cancer received an investigational checkpoint blockade within two months of completing treatment with CDX-1401 and both achieved partial responses.

The Phase 1 study has identified a well-tolerated and immunogenic regimen to take forward into future studies. We are planning to initiate a Phase 1/2 study of varlilumab and ipilimumab plus CDX-1401 in NY-ESO+ patients with metastatic melanoma in the second half of 2014. In addition, Celldex will provide support for a collaborative Phase 2 study of CDX-1401 in combination with CDX-301 in metastatic melanoma. This study will be conducted by the Cancer Immunotherapy Trials Network under a cooperative research and development agreement, or CRADA, with the Cancer Therapy Evaluation Program of the National Cancer Institute and is expected to begin enrolling patients in the third quarter of 2014.

CDX-301

CDX-301 is a FMS-like tyrosine kinase 3 ligand, or Flt3L, stem cell mobilizer and dendritic cell growth factor. We licensed CDX-301 from Amgen Inc. in March 2009. CDX-301 is a potent hematopoietic cytokine that stimulates the expansion and differentiation of hematopoietic progenitor and stem cells. CDX-301 has demonstrated a unique capacity to increase the number of circulating dendritic cells in both laboratory and clinical studies. In addition, CDX-301 has shown impressive results in models of cancer, infectious diseases and inflammatory/autoimmune

Edgar Filing: Celldex Therapeutics, Inc. - Form 10-Q

diseases. We believe CDX-301 may hold significant opportunity for synergistic development in combination with other proprietary molecules in our portfolio.

In February 2013, we announced final results from our dose-escalating Phase 1 study of CDX-301 in 30 healthy subjects in collaboration with Rockefeller University. The Phase 1 study evaluated seven different dosing regimens of CDX-301 to determine the appropriate dose for further development based on safety, tolerability, and biological activity. The data from the study were consistent with previous clinical experience and demonstrated that CDX-301 was well-tolerated and can effectively mobilize hematopoietic stem cell populations in healthy volunteers. In December 2013, we announced data from a preclinical combination study of CDX-301 and Mozobil® (Plerixafor injection, formerly AMD3100) demonstrating that the combination of these agents significantly increases hematopoietic stem cell mobilization in mice. The data demonstrate a novel potent cell mobilization regimen combining CDX-301 and Mozobil®, which may have significant potential for use in autologous and allogeneic hematopoietic stem cell transplantation. Based on the safety profile and the clinical and preclinical data to date, we plan to initiate a pilot clinical study of CDX-301 as a single-agent and in combination with Mozobil in the transplant setting in the third quarter of 2014.

Table of Contents**Preclinical Programs***CDX-014*

CDX-014 is a fully-human monoclonal ADC that targets TIM-1, a molecule that is upregulated in several cancers, including renal cell and ovarian carcinomas. It is associated with kidney injury and the shedding of its ectodomain is a predictive biomarker for tumor progression. TIM-1 has very restricted expression in healthy tissues, making it a promising target for antibody mediated therapy. The antibody is linked to MMAE using Seattle Genetics' proprietary technology. The ADC is designed to be stable in the bloodstream, but to release MMAE upon internalization into TIM-1-expressing tumor cells, resulting in a targeted cell-killing effect. CDX-014 has shown potent activity in preclinical models of ovarian and renal cancer. We have established preclinical proof-of-concept and are completing manufacturing and IND-enabling studies to support the initiation of Phase 1 clinical studies in renal cell carcinoma and potentially other TIM-1 expressing tumors in 2015.

CRITICAL ACCOUNTING POLICIES

Our critical accounting policies are more fully described in Note 2 to our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2013 and there have been no material changes to such critical accounting policies. We believe our most critical accounting policies include accounting for business combinations, revenue recognition, impairment of long-lived assets, research and development expenses and stock-based compensation expense.

RESULTS OF OPERATIONS*Three Months Ended June 30, 2014 compared with Three Months Ended June 30, 2013*

| | Three Months Ended June 30, | | Increase/ (Decrease) | | Increase/ (Decrease) | |
|--|--------------------------------|----------|-------------------------|--|-------------------------|--|
| | 2014 | 2013 | \$ | | % | |
| (In thousands) | | | | | | |
| Revenue: | | | | | | |
| Product Development and Licensing | | | | | | |
| Agreements | \$ 200 | \$ 47 | \$ 153 | | 326% | |
| Contracts and Grants | 392 | 50 | 342 | | 684% | |
| Total Revenue | \$ 592 | \$ 97 | \$ 495 | | 510% | |
| Operating Expense: | | | | | | |
| Research and Development | 24,100 | 15,090 | 9,010 | | 60% | |
| General and Administrative | 4,787 | 3,411 | 1,376 | | 40% | |
| Amortization of Acquired Intangible Assets | 254 | 254 | | | 0% | |
| Total Operating Expense | 29,141 | 18,755 | 10,386 | | 55% | |
| Operating Loss | (28,549) | (18,658) | 9,891 | | 53% | |
| Investment and Other Income, Net | 275 | 161 | 114 | | 71% | |
| Interest Expense | | (519) | (519) | | (100)% | |

Edgar Filing: Celldex Therapeutics, Inc. - Form 10-Q

| | | | | | | | |
|----------|----|----------|----|----------|----|-------|-----|
| Net Loss | \$ | (28,274) | \$ | (19,016) | \$ | 9,258 | 49% |
|----------|----|----------|----|----------|----|-------|-----|

Net Loss

The \$9.3 million increase in net loss for the three months ended June 30, 2014 compared to the three months ended June 30, 2013 was primarily the result of an increase in research and development and general and administrative expenses.

Revenue

The \$0.2 million increase in product development and licensing agreements revenue for the three months ended June 30, 2014 compared to the three months ended June 30, 2013 was primarily related to our BMS agreement. In May 2014, we entered into a clinical trial collaboration with BMS whereby BMS made a one-time payment to us of \$5.0 million which we are recognizing as revenue over our estimated performance period. The \$0.3 million increase in contracts and grants revenue for the three months ended June 30, 2014 compared to the three months ended June 30, 2013 was primarily related to our Rockefeller University agreement pursuant to which we perform research and development services for Rockefeller. The agreement includes an approved project plan for the development services of \$4.8 million and a term of three years.

Edgar Filing: Celldex Therapeutics, Inc. - Form 10-Q

Table of Contents

Research and Development Expense

Research and development expenses consist primarily of (i) personnel expenses, (ii) laboratory supply expenses relating to the development of our technology, (iii) facility expenses, (iv) license fees and (v) product development expenses associated with our product candidates as follows:

| | Three Months Ended June 30, | | Increase/ (Decrease) | | Increase/ (Decrease) | |
|---------------------|--------------------------------|----------|-------------------------|--|-------------------------|------|
| | 2014 | 2013 | (In thousands) | | | |
| | | | | | \$ | % |
| Personnel | \$ 4,831 | \$ 3,835 | | | \$ 996 | 26% |
| Laboratory Supplies | 845 | 929 | | | (84) | (9)% |
| Facility | 1,358 | 1,142 | | | 216 | 19% |
| License Fees | 74 | 69 | | | 5 | 7% |
| Product Development | 15,871 | 8,569 | | | 7,302 | 85% |

Personnel expenses primarily include salary, benefits, stock-based compensation and payroll taxes. The \$1.0 million increase in personnel expenses for the three months ended June 30, 2014 compared to the three months ended June 30, 2013 was primarily due to higher stock-based compensation of \$0.3 million and increased headcount. We expect personnel expenses to increase over the next twelve months as we plan to continue to increase our headcount, primarily to support our rindopepimut, glembatumumab vedotin and varlilumab programs.

Laboratory supply expenses include laboratory materials and supplies, services, and other related expenses incurred in the development of our technology. The \$0.1 million decrease in laboratory supply expense for the three months ended June 30, 2014 compared to the three months ended June 30, 2013 was primarily due to lower manufacturing supply purchases. We expect supply expenses to remain relatively consistent over the next twelve months, although there may be fluctuations on a quarterly basis.

Facility expenses include depreciation, amortization, utilities, rent, maintenance, and other related expenses incurred at our facilities. The \$0.2 million increase in facility expenses for the three months ended June 30, 2014 compared to the three months ended June 30, 2013 was primarily due to an increase in amortization expense related to the leasehold improvements made at our headquarters facility in Hampton, New Jersey. We expect facility expenses to remain relatively consistent over the next twelve months, although there may be fluctuations on a quarterly basis.

License fee expenses include annual license maintenance fees and milestone payments due upon the achievement of certain development, regulatory and/or commercial milestones. License fee expenses for the three months ended June 30, 2014 were relatively consistent compared to the three months ended June 30, 2013. We expect license fee expense to remain relatively consistent over the next twelve months.

Product development expenses include clinical investigator site fees, external trial monitoring costs, data accumulation costs, contracted research and outside clinical drug product manufacturing. The \$7.3 million increase in product development expenses for the three months ended June 30, 2014 compared to the three months ended June 30, 2013 was primarily the result of an increase in clinical trial costs and contract manufacturing of \$1.4 million and \$5.8 million, respectively, primarily related to our rindopepimut and glembatumumab vedotin programs. We expect product development expenses to increase over the next twelve months primarily due to the increase in clinical trial and contract manufacturing expenses related to our rindopepimut, glembatumumab vedotin and varlilumab programs, although there may be fluctuations on a

quarterly basis.

General and Administrative Expense

The \$1.4 million increase in general and administrative expenses for the three months ended June 30, 2014 compared to the three months ended June 30, 2013 was primarily due to higher stock-based compensation of \$0.5 million, increased headcount and rindopepimut and glembatumumab vedotin commercial planning costs. We expect general and administrative expense to increase over the next twelve months primarily due to increased commercial planning efforts for rindopepimut and glembatumumab vedotin, although there may be fluctuations on a quarterly basis.

Amortization Expense

Amortization expenses for the three months ended June 30, 2014 were relatively consistent compared to the three months ended June 30, 2013. We expect amortization expense of acquired intangible assets to remain relatively consistent over the next twelve months.

The \$0.1 million increase in investment and other income, net for the three months ended June 30, 2014 compared to the three months ended June 30, 2013 was primarily due to higher cash and investment balances. We anticipate other income to increase over the next twelve months due to the anticipated receipt of a \$2.0 million milestone payment from TopoTarget. This payment is the last milestone payment we are owed from TopoTarget and was triggered in July 2014 upon the FDA approval of Beleodaq (belinostat).

The \$0.5 million decrease in interest expense for the three months ended June 30, 2014 compared to the three months ended June 30, 2013 was primarily due to our election in May 2013 to prepay our term loan in full, pursuant to the terms of our loan agreement.

| | Six Months Ended June 30, | | | Increase/ (Decrease) \$ | Increase/ (Decrease) % |
|--|------------------------------|-------------|----------------|-------------------------------|------------------------------|
| | 2014 | 2013 | (In thousands) | | |
| Revenue: | | | | | |
| Product Development and Licensing | | | | | |
| Agreements | \$ 235 | \$ 77 | | \$ 158 | 205% |
| Contracts and Grants | 773 | 100 | | 673 | 673% |
| Product Royalties | | 2,334 | | (2,334) | (100)% |
| Total Revenue | \$ 1,008 | \$ 2,511 | | \$ (1,503) | (60)% |
| Operating Expense: | | | | | |
| Research and Development | 51,169 | 29,180 | | 21,989 | 75% |
| Royalty | | 2,334 | | (2,334) | (100)% |
| General and Administrative | 9,369 | 6,549 | | 2,820 | 43% |
| Amortization of Acquired Intangible Assets | 507 | 507 | | | 0% |
| Total Operating Expense | 61,045 | 38,570 | | 22,475 | 58% |
| Operating Loss | (60,037) | (36,059) | | 23,978 | 66% |
| Investment and Other Income, Net | 1,860 | 540 | | 1,320 | 244% |
| Interest Expense | | (829) | | (829) | (100)% |
| Net Loss | \$ (58,177) | \$ (36,348) | | \$ 21,829 | 60% |

The \$21.8 million increase in net loss for the six months ended June 30, 2014 compared to the six months ended June 30, 2013 was primarily the result of an increase in research and development and general and administrative expenses.

Revenue

The \$0.2 million increase in product development and licensing agreements revenue for the six months ended June 30, 2014 compared to the six months ended June 30, 2013 was primarily related to our BMS agreement. The \$0.7 million increase in contracts and grants revenue for the six months ended June 30, 2014 compared to the six months ended June 30, 2013 was primarily related to our Rockefeller University agreement. The \$2.3 million decrease in product royalty revenue for the six months ended June 30, 2014 compared to the six months ended June 30, 2013 was due to the termination of our agreement with GlaxoSmithKline plc upon the expiration of the last relevant patent right covered by the agreement. The terminated retained interests in Rotarix® net royalties which were not sold to Paul Royalty Fund II, L.P. had been equal to the amount payable to Cincinnati Children's Hospital Medical Center and recognized as royalty expense by us.

Edgar Filing: Celldex Therapeutics, Inc. - Form 10-Q

Table of Contents

Research and Development Expense

| | Six Months Ended June 30, | | Increase/ (Decrease) | | Increase/ (Decrease) | |
|---------------------|------------------------------|----------|-------------------------|--|-------------------------|--|
| | 2014 | 2013 | | | | |
| | (In thousands) | | | | | |
| Personnel | \$ 9,292 | \$ 7,618 | \$ 1,674 | | 22% | |
| Laboratory Supplies | 1,669 | 1,641 | 28 | | 2% | |
| Facility | 2,559 | 2,259 | 300 | | 13% | |
| License Fees | 2,683 | 138 | 2,545 | | 1,844% | |
| Product Development | 33,024 | 16,384 | 16,640 | | 102% | |

The \$1.7 million increase in personnel expenses for the six months ended June 30, 2014 compared to the six months ended June 30, 2013 was primarily due to higher stock-based compensation of \$0.5 million and increased headcount.

Laboratory supply expense for the six months ended June 30, 2014 was relatively consistent as compared to the six months ended June 30, 2013.

The \$0.3 million increase in facility expenses for the six months ended June 30, 2014 compared to the six months ended June 30, 2013 was primarily due to an increase in amortization expense related to the leasehold improvements made at our headquarters facility in Hampton, New Jersey.

The \$2.5 million increase in license fee expenses for the six months ended June 30, 2014 compared to the six months ended June 30, 2013 was due to the one-time \$2.5 million milestone incurred and paid to Seattle Genetics as a result of the METRIC initiation.

The \$16.6 million increase in product development expenses for the six months ended June 30, 2014 compared to the six months ended June 30, 2013 was primarily the result of an increase in clinical trial costs and contract manufacturing of \$7.7 million and \$8.7 million, respectively, primarily related to our rindopepimut and glembatumumab vedotin programs.

Royalty Expense

The \$2.3 million decrease in royalty expenses for the six months ended June 30, 2014 compared to the six months ended June 30, 2013 was due to the termination of our agreement with GlaxoSmithKline plc upon the expiration of the last relevant patent right covered by the agreement.

General and Administrative Expense

Edgar Filing: Celldex Therapeutics, Inc. - Form 10-Q

The \$2.8 million increase in general and administrative expenses for the six months ended June 30, 2014 compared to the six months ended June 30, 2013 was primarily due to higher stock-based compensation of \$0.9 million, increased headcount and rindopepimut and glembatumumab vedotin commercial planning costs.

Amortization Expense

Amortization expenses for the six months ended June 30, 2014 was relatively consistent as compared to the six months ended June 30, 2013.

Investment and Other Income, Net

The \$1.3 million increase in investment and other income, net for the six months ended June 30, 2014 compared to the six months ended June 30, 2013 was primarily due to \$1.0 million received in February 2014 in connection with our TopoTarget agreement and us recognizing \$0.4 million and \$0.2 million in other income related to the sale of New Jersey tax benefits during the six months ended June 30, 2014 and 2013, respectively.

Interest Expense

The \$0.8 million decrease in interest expense for the six months ended June 30, 2014 compared to the six months ended June 30, 2013 was primarily due to our election in May 2013 to prepay our term loan in full, pursuant to the terms of our loan agreement.

LIQUIDITY AND CAPITAL RESOURCES

Our cash equivalents are highly liquid investments with a maturity of three months or less at the date of purchase and consist primarily of investments in money market mutual funds with commercial banks and financial institutions. We maintain cash balances

Table of Contents

with financial institutions in excess of insured limits. We do not anticipate any losses with respect to such cash balances. We invest our excess cash balances in marketable securities including municipal bond securities, U.S. government agency securities, and high-grade corporate bonds that meet high credit quality standards, as specified in our investment policy. Our investment policy seeks to manage these assets to achieve our goals of preserving principal and maintaining adequate liquidity.

The use of our cash flows for operations has primarily consisted of salaries and wages for our employees, facility and facility-related costs for our offices, laboratories and manufacturing facility, fees paid in connection with preclinical studies, clinical studies, contract manufacturing, laboratory supplies and services, consulting, legal and other professional fees. To date, the primary sources of cash flows from operations have been payments received from our collaborative partners and from government entities. The timing of any new collaboration agreements, government contracts or grants and any payments under these agreements, contracts or grants cannot be easily predicted and may vary significantly from quarter to quarter.

At June 30, 2014, our principal sources of liquidity consisted of cash, cash equivalents and marketable securities of \$252.4 million. We incurred a loss of \$58.2 million for the six months ended June 30, 2014. Net cash used in operations for the six months ended June 30, 2014 was \$52.7 million. We believe that the cash, cash equivalents and marketable securities at June 30, 2014 are sufficient to meet estimated working capital requirements and fund planned operations for more than the next two years.

During the next twelve months, we may take further steps to raise additional capital to meet our long-term liquidity needs. Our capital raising activities may include, but may not be limited to, one or more of the following: the licensing of technology programs with existing or new collaborative partners, possible business combinations, issuance of debt, or the issuance of common stock or other securities via private placements or public offerings. While we continue to seek capital through a number of means, there can be no assurance that additional financing will be available on acceptable terms, if at all, and our negotiating position in capital-raising efforts may worsen as existing resources are used. There is also no assurance that we will be able to enter into further collaborative relationships. Additional equity financing may be dilutive to our stockholders; debt financing, if available, may involve significant cash payment obligations and covenants that restrict our ability to operate as a business; and licensing or strategic collaborations may result in royalties or other terms which reduce our economic potential from products under development.

Operating Activities

Net cash used in operating activities was \$52.7 million for the six months ended June 30, 2014 compared to \$35.3 million for the six months ended June 30, 2013. The increase in net cash used in operating activities was primarily due to an increase in net loss of \$22.3 million and changes in working capital. We expect that cash used in operations will continue to increase over the next twelve months primarily related to costs incurred on our rindopepimut and glembatumumab vedotin programs.

We have incurred and will continue to incur significant costs in the area of research and development, including preclinical and clinical trials, as our product candidates are developed. We plan to spend significant amounts to progress our current product candidates through the clinical trial and commercialization process as well as to develop additional product candidates. As our product candidates progress through the clinical trial process, we may be obligated to make significant milestone payments.

Investing Activities

Net cash used in investing activities was \$76.7 million for the six months ended June 30, 2014 compared to \$69.2 million for the six months ended June 30, 2013. The increase in net cash used in investing activities was primarily due to net purchases of marketable securities for the six months ended June 30, 2014 of \$75.6 million as compared to \$68.3 million for the six months ended June 30, 2013.

Financing Activities

Net cash provided by financing activities was \$0.9 million for the six months ended June 30, 2014 compared to \$105.4 million for the six months ended June 30, 2013. Net proceeds from stock issuances, including stock issued pursuant to employee benefit plans, were \$0.9 million during the six months ended June 30, 2014 compared to \$116.5 million for the six months ended June 30, 2013. We paid \$11.0 million in principal payments on our Term Loan during the six months ended June 30, 2013.

Equity Offerings

During the six months ended June 30, 2013, we issued 2,433,608 shares of our common stock under our controlled equity offering sales agreement with Cantor Fitzgerald & Co., as amended, resulting in net proceeds to us of \$17.1 million, after deducting commission and offering expenses.

Table of Contents

During the six months ended June 30, 2013, we issued 13,800,000 shares of our common stock in an underwritten public offering resulting in net proceeds to us of \$97.0 million, after deducting underwriting fees and offering expenses.

AGGREGATE CONTRACTUAL OBLIGATIONS

Except as set forth below, the disclosures relating to our contractual obligations reported in our Annual Report on Form 10-K for the year ended December 31, 2013 which was filed with the SEC on March 8, 2013 have not materially changed since we filed that report.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Risk

We own financial instruments that are sensitive to market risk as part of our investment portfolio. Our investment portfolio is used to preserve our capital until it is used to fund operations, including our research and development activities. None of these market-risk sensitive instruments are held for trading purposes. We invest our cash primarily in money market mutual funds. These investments are evaluated quarterly to determine the fair value of the portfolio. From time to time, we invest our excess cash balances in marketable securities including municipal bond securities, U.S. government agency securities, and high-grade corporate bonds that meet high credit quality standards, as specified in our investment policy. Our investment policy seeks to manage these assets to achieve our goals of preserving principal and maintaining adequate liquidity. Because of the short-term nature of these investments, we do not believe we have material exposure due to market risk. The impact to our financial position and results of operations from likely changes in interest rates is not material.

We do not utilize derivative financial instruments. The carrying amounts reflected in the consolidated balance sheet of cash and cash equivalents, accounts receivables and accounts payable approximates fair value at June 30, 2014 due to the short-term maturities of these instruments.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures.

As of June 30, 2014, we evaluated, with the participation of our Chief Executive Officer and Chief Financial Officer, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act)). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of June 30, 2014. Our disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded,

Edgar Filing: Celldex Therapeutics, Inc. - Form 10-Q

processed, summarized and reported within time periods specified by the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting.

There were no changes in our internal control over financial reporting during the three months ended June 30, 2014 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II OTHER INFORMATION

Item 1A. Risk Factors

In addition to the other information set forth in this report, you should carefully consider the factors discussed in Part I, Item 1A. Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2013, which could materially affect our business, financial condition or future results. The risks described in our Annual Report on Form 10-K may not be the only risks facing the Company. Additional risks and uncertainties not currently known to the Company or that the Company currently deems to be immaterial also may materially adversely affect the Company's business, financial condition and/or operating results.

There were no material changes to the risk factors previously disclosed in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 3, 2014.

Table of Contents

Item 6. Exhibits

- 3.1 Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.1 of the Company's Registration Statement on Form S-4 (Reg. No. 333-59215), filed July 16, 1998 with the Securities and Exchange Commission.
- 3.2 Certificate of Amendment of Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.1 of the Company's Registration Statement on Form S-4 (Reg. No. 333-59215), filed July 16, 1998 with the Securities and Exchange Commission.
- 3.3 Second Certificate of Amendment of Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.2 of the Company's Registration Statement on Form S-4 (Reg. No. 333-59215), filed July 16, 1998 with the Securities and Exchange Commission.
- 3.4 Third Certificate of Amendment of Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.1 of the Company's Quarterly Report on Form 10-Q, filed May 10, 2002 with the Securities and Exchange Commission.
- 3.5 Fourth Certificate of Amendment of Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K, filed on March 11, 2008 with the Securities and Exchange Commission.
- 3.6 Fifth Certificate of Amendment of Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.2 of the Company's Current Report on Form 8-K, filed on March 11, 2008 with the Securities and Exchange Commission.
- 3.7 Sixth Certificate of Amendment of Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.7 of the Company's Quarterly Report on Form 10-Q, filed November 10, 2008 with the Securities and Exchange Commission.
- 4.3 Amendment No. 2 to Shareholder Rights Agreement dated November 5, 2004, between the Company and Computershare Trust Company, N.A. (formerly EquiServe Trust Company, N.A.), as Rights Agent, incorporated by reference to Exhibit 10.1 of the Company's Registration Statement on Form 8-A1G/A, filed on March 7, 2008 with the Securities and Exchange Commission.
- *31.1 Certification of President and Chief Executive Officer
- *31.2 Certification of Senior Vice President and Chief Financial Officer
- **32.1 Section 1350 Certifications
- 101.1+ XBRL Instance Document.
- 101.2+ XBRL Taxonomy Extension Schema Document.
- 101.3+ XBRL Taxonomy Extension Calculation Linkbase Document.
- 101.4+ XBRL Taxonomy Extension Definition Linkbase Document.
- 101.5+ XBRL Taxonomy Extension Label Linkbase Document.
- 101.6+ XBRL Taxonomy Extension Presentation Linkbase Document.

* Filed herewith.

** Furnished herewith.

+ The XBRL information is being furnished and not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not incorporated by reference into any registration statement under the Securities Act of 1933, as amended.

Table of Contents

SIGNATURES

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

CELLEX THERAPEUTICS, INC.

BY:

Dated: August 7, 2014

/s/ ANTHONY S. MARUCCI
Anthony S. Marucci
President and Chief Executive Officer
(Principal Executive Officer)

Dated: August 7, 2014

/s/ AVERY W. CATLIN
Avery W. Catlin
Senior Vice President, Treasurer and Chief Financial Officer
(Principal Financial and Accounting Officer)

Table of Contents

EXHIBIT INDEX

| Exhibit No. | Description |
|--------------------|--|
| 3.1 | Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.1 of the Company's Registration Statement on Form S-4 (Reg. No. 333-59215), filed July 16, 1998 with the Securities and Exchange Commission. |
| 3.2 | Certificate of Amendment of Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.1 of the Company's Registration Statement on Form S-4 (Reg. No. 333-59215), filed July 16, 1998 with the Securities and Exchange Commission. |
| 3.3 | Second Certificate of Amendment of Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.2 of the Company's Registration Statement on Form S-4 (Reg. No. 333-59215), filed July 16, 1998 with the Securities and Exchange Commission. |
| 3.4 | Third Certificate of Amendment of Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.1 of the Company's Quarterly Report on Form 10-Q, filed May 10, 2002 with the Securities and Exchange Commission. |
| 3.5 | Fourth Certificate of Amendment of Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K, filed on March 11, 2008 with the Securities and Exchange Commission. |
| 3.6 | Fifth Certificate of Amendment of Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.2 of the Company's Current Report on Form 8-K, filed on March 11, 2008 with the Securities and Exchange Commission. |
| 3.7 | Sixth Certificate of Amendment of Third Restated Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.7 of the Company's Quarterly Report on Form 10-Q, filed November 10, 2008 with the Securities and Exchange Commission. |
| 4.3 | Amendment No. 2 to Shareholder Rights Agreement dated November 5, 2004, between the Company and Computershare Trust Company, N.A. (formerly EquiServe Trust Company, N.A.) as Rights Agent, incorporated by reference to Exhibit 10.1 of the Company's Registration Statement on Form 8-A1G/A, filed on March 7, 2008 with the Securities and Exchange Commission. |
| *31.1 | Certification of President and Chief Executive Officer |
| *31.2 | Certification of Senior Vice President and Chief Financial Officer |
| **32.1 | Section 1350 Certifications |
| 101.1+ | XBRL Instance Document. |
| 101.2+ | XBRL Taxonomy Extension Schema Document. |
| 101.3+ | XBRL Taxonomy Extension Calculation Linkbase Document. |
| 101.4+ | XBRL Taxonomy Extension Definition Linkbase Document. |
| 101.5+ | XBRL Taxonomy Extension Label Linkbase Document. |
| 101.6+ | XBRL Taxonomy Extension Presentation Linkbase Document. |
| <hr/> | |
| * | Filed herewith. |
| ** | Furnished herewith. |
| + | The XBRL information is being furnished and not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not incorporated by reference into any registration statement under the Securities Act of 1933, as amended. |