# CELLDEX THERAPEUTICS, INC.

## FORM 10-Q
(Quarterly Report)

Filed 05/10/18 for the Period Ending 03/31/18

| | |
|---|---|
| Address | 53 FRONTAGE ROAD<br>SUITE 220<br>HAMPTON, NJ, 08827 |
| Telephone | 908-200-7500 |
| CIK | 0000744218 |
| Symbol | CLDX |
| SIC Code | 2835 - In Vitro and In Vivo Diagnostic Substances |
| Industry | Biotechnology & Medical Research |
| Sector | Healthcare |
| Fiscal Year | 12/31 |

# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# FORM 10-Q

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

**For the quarterly period ended March 31, 2018**

**OR**

☐ **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)

| **Delaware** | **No. 13-3191702** |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth 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 ☐ Emerging growth company ☐ |

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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 May 3, 2018, 143,392,841 shares of common stock, $.001 par value per share, were outstanding.

**CELLDEX THERAPEUTICS, INC.**

**FORM 10-Q**

**For the Quarterly Period Ended March 31, 2018**

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**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)**

| | March 31, 2018 | December 31, 2017 |
|---|---|---|
| **ASSETS** | | |
| Current Assets: | | |
| Cash and Cash Equivalents | $ 39,824 | $ 40,288 |
| Marketable Securities | 83,424 | 99,139 |
| Accounts and Other Receivables | 4,020 | 1,880 |
| Prepaid and Other Current Assets | 3,704 | 3,449 |
| Total Current Assets | 130,972 | 144,756 |
| Property and Equipment, Net | 9,785 | 10,372 |
| Intangible Assets, Net | 48,690 | 67,591 |
| Other Assets | 1,929 | 1,929 |
| Goodwill | — | 90,976 |
| Total Assets | $ 191,376 | $ 315,624 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current Liabilities: | | |
| Accounts Payable | $ 508 | $ 1,715 |
| Accrued Expenses | 14,897 | 19,455 |
| Current Portion of Long-Term Liabilities | 8,607 | 6,566 |
| Total Current Liabilities | 24,012 | 27,736 |
| Other Long-Term Liabilities | 33,282 | 51,519 |
| Total Liabilities | 57,294 | 79,255 |
| Commitments and Contingent Liabilities | | |
| Stockholders' Equity: | | |
| Convertible Preferred Stock, $.01 Par Value; 3,000,000 Shares Authorized; No Shares Issued and Outstanding at March 31, 2018 and December 31, 2017 | — | — |
| Common Stock, $.001 Par Value; 297,000,000 Shares Authorized; 143,368,784 and 138,520,404 Shares Issued and Outstanding at March 31, 2018 and December 31, 2017, Respectively | 143 | 139 |
| Additional Paid-In Capital | 1,060,768 | 1,046,183 |
| Accumulated Other Comprehensive Income | 2,559 | 2,564 |
| Accumulated Deficit | (929,388) | (812,517) |
| Total Stockholders' Equity | 134,082 | 236,369 |
| Total Liabilities and Stockholders' Equity | $ 191,376 | $ 315,624 |

See accompanying notes to unaudited condensed consolidated financial statements

**CELLDEX THERAPEUTICS, INC.**
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**
**(Unaudited)**

**(In thousands, except per share amounts)**

| | Three Months Ended March 31, 2018 | Three Months Ended March 31, 2017 |
|---|---|---|
| **REVENUES:** | | |
| Product Development and Licensing Agreements | $ 992 | $ 556 |
| Contracts and Grants | 3,076 | 978 |
| Total Revenues | 4,068 | 1,534 |
| | | |
| **OPERATING EXPENSES:** | | |
| Research and Development | 21,875 | 25,793 |
| General and Administrative | 5,593 | 7,229 |
| Goodwill Impairment | 90,976 | — |
| Intangible Asset Impairment | 18,677 | — |
| (Gain)/Loss on Fair Value Remeasurement of Contingent Consideration | (13,600) | 3,400 |
| Amortization of Acquired Intangible Assets | 224 | 224 |
| Total Operating Expenses | 123,745 | 36,646 |
| | | |
| Operating Loss | (119,677) | (35,112) |
| Investment and Other Income, Net | 780 | 851 |
| Net Loss Before Income Tax Benefit | $ (118,897) | $ (34,261) |
| Income Tax Benefit | 765 | — |
| Net Loss | $ (118,132) | $ (34,261) |
| | | |
| Basic and Diluted Net Loss Per Common Share | $ (0.84) | $ (0.28) |
| | | |
| Shares Used in Calculating Basic and Diluted Net Loss per Share | 140,548 | 122,648 |
| | | |
| **COMPREHENSIVE LOSS:** | | |
| Net Loss | $ (118,132) | $ (34,261) |
| Other Comprehensive Income (Loss): | | |
| Unrealized Gain (Loss) on Marketable Securities | (5) | 21 |
| Comprehensive Loss | $ (118,137) | $ (34,240) |

See accompanying notes to unaudited condensed consolidated financial statements

**CELLDEX THERAPEUTICS, INC.**
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOW**
**(Unaudited)**

**(In thousands)**

| | Three Months Ended March 31, 2018 | Three Months Ended March 31, 2017 |
|---|---|---|
| **Cash Flows From Operating Activities:** | | |
| Net Loss | $ (118,132) | $ (34,261) |
| Adjustments to Reconcile Net Loss to Net Cash Used in Operating Activities: | | |
| Depreciation and Amortization | 1,028 | 1,366 |
| Amortization of Intangible Assets | 224 | 224 |
| Amortization and Premium of Marketable Securities, Net | (155) | (23) |
| Loss on Sale or Disposal of Assets | 10 | — |
| Goodwill Impairment | 90,976 | — |
| Intangible Asset Impairment | 18,677 | — |
| (Gain)/Loss on Fair Value Remeasurement of Contingent Consideration | (13,600) | 3,400 |
| Non-Cash Income Tax Benefit | (765) | — |
| Stock-Based Compensation Expense | 2,488 | 3,539 |
| Non-Cash Expense | — | — |
| Changes in Operating Assets and Liabilities: | | |
| Accounts and Other Receivables | (1,635) | 400 |
| Prepaid and Other Current Assets | (144) | (989) |
| Other Assets | — | 199 |
| Accounts Payable and Accrued Expenses | (5,919) | (8,315) |
| Other Liabilities | (1,075) | (802) |
| Net Cash Used in Operating Activities | (28,022) | (35,262) |
| **Cash Flows From Investing Activities:** | | |
| Sales and Maturities of Marketable Securities | 46,871 | 73,736 |
| Purchases of Marketable Securities | (31,117) | (50,961) |
| Acquisition of Property and Equipment | (259) | (374) |
| Net Cash Provided by Investing Activities | 15,495 | 22,401 |
| **Cash Flows From Financing Activities:** | | |
| Net Proceeds from Stock Issuances | 11,689 | 12,821 |
| Proceeds from Issuance of Stock from Employee Benefit Plans | 374 | 76 |
| Net Cash Provided by Financing Activities | 12,063 | 12,897 |
| Net (Decrease) Increase in Cash and Cash Equivalents | (464) | 36 |
| Cash and Cash Equivalents at Beginning of Period | 40,288 | 42,461 |
| Cash and Cash Equivalents at End of Period | $ 39,824 | $ 42,497 |
| *Non-cash Investing Activities* | | |
| Accrued construction in progress | $ 212 | $ 370 |
| *Non-cash Supplemental Disclosure* | | |
| Shares issued to former Kolltan executive for settlement of severance | $ 38 | $ 209 |

See accompanying notes to unaudited condensed consolidated financial statements

**CELLDEX THERAPEUTICS, INC.**
**Notes to Unaudited Condensed Consolidated Financial Statements**
**March 31, 2018**

**(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 whollyowned subsidiaries. All intercompany balances and 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, 2017, which are included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 7, 2018. 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 condensed 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, 2018.

At March 31, 2018, the Company had cash, cash equivalents and marketable securities of $123.2 million. The Company has had recurring losses and incurred a loss of $118.1 million for the three months ended March 31, 2018. Net cash used in operations for the three months ended March 31, 2018 was $28.0 million. The Company believes that the cash, cash equivalents and marketable securities at May 10, 2018 will be sufficient to meet estimated working capital requirements and fund planned operations for at least the next twelve months from the date of issuance of these financial statements.

During the next twelve months and beyond, the Company will take further steps to raise additional capital to meet its liquidity needs. These capital raising activities may include, but may not be limited to, one or more of the following: the licensing of drug candidates 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 may 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 financings 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. The Company's ability to continue funding its planned operations into and beyond twelve months from the issuance date is also dependent on the timing and manner of payment of future contingent milestones from the Kolltan acquisition, in the event that the Company achieves the drug candidate milestones related to those payments. The Company, at its option, may decide to pay those milestone payments in cash, shares of its common stock or a combination thereof. If the Company is unable to raise the funds necessary to meet its liquidity needs, it may have to delay or discontinue the development of one or more programs, discontinue or delay ongoing or anticipated clinical trials, license out programs earlier than expected, raise funds at a significant discount or on other unfavorable terms, if at all, or sell all or a part of the Company.

**(2) Subsequent Events**

On April 16, 2018, the Company announced the failure of its clinical trial ("METRIC") in metastatic triple-negative breast cancer to meet its primary endpoint and decision to discontinue the glembatumumab vedotin ("Glemba") program. The Company considered the METRIC failure and discontinuation of the Glemba program to be a recognized subsequent event that provided additional evidence related to estimates used in preparing the financial statements as of March 31, 2018. Accordingly, for the quarter ended March 31, 2018, the Company recognized (i) an aggregate of $18.7 million in non-cash impairment charges related to fully impairing Glemba-related intangible assets, (ii) a $0.8 million non-cash income tax benefit related to the impaired IPR&D assets, (iii) a $13.6 million gain on the contingent consideration liability related to the METRIC study failure and updated discount rates, and (iv) a $91.0 million goodwill impairment charge as the carrying value of the Company's net assets exceeded the Company's fair value by an amount in excess of the goodwill asset.

On April 24, 2018, the Company approved a reduction in its workforce to reduce operating costs and better align its workforce with the needs of its business. The Company will incur aggregate restructuring charges in the second quarter of 2018 of

approximately $1.3 million related to cash severance payments and other employee-related costs, which will primarily be paid during the second and third quarters of 2018. In the second quarter of 2018, the Company undertook a pipeline prioritization initiative and any adjustments to the fair value of the Kolltan acquisition contingent consideration liabilities resulting from this initiative will be recognized in the second quarter of 2018.

**(3) Significant Accounting Policies**

The significant accounting policies used in preparation of these condensed consolidated financial statements on Form 10-Q for the quarterly period ended March 31, 2018 are consistent with those discussed in Note 2 to the financial statements in our Annual Report on Form 10-K for the year ended December 31, 2017, except as it relates to the adoption of new accounting standards during the first three months of 2018 as discussed below.

*Newly Adopted Accounting Pronouncements*

On January 1, 2018, the Company adopted the new U.S. GAAP standard " *Revenue from Contracts with Customers"* using a modified retrospective application method, recognizing an immaterial cumulative-effect adjustment to accumulated deficit. The Company applied the new guidance to (i) contracts not completed as of the date of adoption and (ii) all new revenue contracts entered into after January 1, 2018. Refer to Note 11 *"Revenue"* for additional details on this adoption and the Company's updated revenue accounting policy and disclosures.

On January 1, 2018, the Company adopted a U.S. GAAP standard update *"Classification of Certain Cash Receipts and Cash Payments"* which clarifies the classification of certain cash receipts and payments in the statement of cash flows. The adoption of this new standard did not impact the Company's consolidated financial statements.

*Recent Accounting Pronouncements*

From time to time, new accounting pronouncements are issued by the 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 consolidated financial statements upon adoption.

In February 2016, the FASB issued a new U.S. GAAP accounting standard which requires that all lessees recognize the assets and liabilities that arise from leases on the balance sheet and disclose qualitative and quantitative information about its leasing arrangements. This new standard will be effective for the Company on January 1, 2019. The Company is currently evaluating the potential impact that this standard may have on the Company's consolidated financial statements.

**(4) Fair Value Measurements**

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

| | As of March 31, 2018 | Level 1 | Level 2 | Level 3 |
|---|---|---|---|---|
| | | (In thousands) | | |
| Assets: | | | | |
| Money market funds and cash equivalents | $ 27,177 | — | $ 27,177 | — |
| Marketable securities | 83,424 | — | 83,424 | — |
| | $ 110,601 | — | $ 110,601 | — |
| Liabilities: | | | | |
| Kolltan acquisition contingent consideration | $ 29,800 | — | — | $ 29,800 |
| | $ 29,800 | — | — | $ 29,800 |

| | As of December 31, 2017 | Level 1 | Level 2 | Level 3 |
|---|---|---|---|---|
| | | (In thousands) | | |
| Assets: | | | | |
| Money market funds and cash equivalents | $ 24,061 | — | $ 24,061 | — |
| Marketable securities | 99,139 | — | 99,139 | — |
| | $ 123,200 | — | $ 123,200 | — |
| Liabilities: | | | | |
| Kolltan acquisition contingent consideration | $ 43,400 | — | — | $ 43,400 |
| | $ 43,400 | — | — | $ 43,400 |

The Company's financial assets consist mainly of money market funds and cash equivalents and marketable securities and are classified as Level 2 within the valuation hierarchy. 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 each balance sheet date, observable market inputs may include trade information, broker or dealer quotes, bids, offers or a combination of these data sources.

The following table reflects the activity for the Company's contingent consideration liabilities measured at fair value using Level 3 inputs for the three months ended March 31, 2018 (in thousands):

| | Other Liabilities: Contingent Consideration |
|---|---|
| Balance at December 31, 2017 | $ 43,400 |
| Fair value adjustments included in operating expenses | (13,600) |
| Balance at March 31, 2018 | $ 29,800 |

The valuation technique used to measure fair value of the Company's Level 3 liabilities, which consist of contingent consideration related to the acquisition of Kolltan in 2016, was primarily an income approach. The Company may be required to pay future consideration of up to $172.5 million that is contingent upon the achievement of specified development, regulatory approvals or sales-based milestone events. The significant unobservable inputs used in the fair value measurement of the contingent consideration are estimates including probability of success, discount rates and amount of time until the conditions of the milestone payments are met. During the three months ended March 31, 2018, the Company recorded a $13.6 million gain on fair value remeasurement of contingent consideration, primarily due to updated assumptions for Glemba-related milestones and discount rates due to the METRIC failure and discontinuation of the Glemba program. During the three months ended March 31, 2017, the Company recorded a $3.4 million loss on fair value remeasurement of contingent consideration, primarily due to changes in discount rates and the passage of time.

The Company did not have any transfers of assets or liabilities between the fair value measurement classifications during the three months ended March 31, 2018.

**(5) Marketable Securities**

The following is a summary of marketable securities, classified as available-for-sale:

| | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
|---|---|---|---|---|
| | (In thousands) | | | |
| **March 31, 2018** | | | | |
| U.S. government and municipal obligations (maturing in one year or less) | $ 24,150 | $ 2 | $ (7) | $ 24,145 |
| Corporate debt securities (maturing in one year or less) | 59,311 | — | (32) | $ 59,279 |
| Total Marketable Securities | $ 83,461 | $ 2 | $ (39) | $ 83,424 |
| | | | | |
| **December 31, 2017** | | | | |
| U.S. government and municipal obligations (maturing in one year or less) | $ 26,164 | $ 3 | $ (9) | $ 26,158 |
| Corporate debt securities (maturing in one year or less) | 73,007 | 1 | (27) | 72,981 |
| Total Marketable Securities | $ 99,171 | $ 4 | $ (36) | $ 99,139 |

The Company holds investment-grade marketable securities, and none were in a continuous unrealized loss position for more than 12 months as of March 31, 2018 and December 31, 2017. The unrealized losses are attributable to changes in interest rates and the Company does not believe any unrealized losses represent other-than-temporary impairments.

Marketable securities include $0.2 million and $0.3 million in accrued interest at March 31, 2018 and December 31, 2017, respectively.

**(6) Intangible Assets and Goodwill**

*Intangible Assets, Net*

The table below presents information for the Company's finite-lived intangible assets that are subject to amortization and indefinite-lived intangible assets:

| | Gross Carrying Amount | Accumulated Amortization | Impairment | Net Carrying Amount |
|---|---|---|---|---|
| | (In thousands) | | | |
| **March 31, 2018** | | | | |
| Finite-lived Intangible Assets: | | | | |
| License Rights (16 year life) | $ 14,500 | $ (7,623) | $ (6,877) | $ — |
| Indefinite-lived Intangible Assets: | | | | |
| IPR&D | 60,490 | — | (11,800) | 48,690 |
| Total Intangible Assets, Net | $ 74,990 | $ (7,623) | $ (18,677) | $ 48,690 |
| | | | | |
| **December 31, 2017** | | | | |
| Finite-lived Intangible Assets: | | | | |
| License Rights (16 year life) | $ 14,500 | $ (7,399) | $ — | $ 7,101 |
| Indefinite-lived Intangible Assets: | | | | |
| IPR&D | 60,490 | — | — | 60,490 |
| Total Intangible Assets, Net | $ 74,990 | $ (7,399) | $ — | $ 67,591 |

Finite-lived intangible assets consist solely of license rights amended under a 2009 agreement with Amgen Fremont related to developing and commercializing Glemba. The Company evaluated the intangible asset for potential impairment related to the discontinuation of the Glemba program. The carrying value of the intangible asset was determined to be fully impaired and a non-cash impairment charge of $6.9 million was recorded for the three months ended March 31, 2018. Amortization expense related to this finite-lived intangible asset was $0.2 million for each of the three-month periods ended March 31, 2018 and 2017.

Indefinite-lived intangible assets consist of acquired in-process research and development ("IPR&D") related to the development of Glemba, CDX-3379, the anti-KIT program and the TAM program. The Company performs an impairment test on IPR&D assets at least annually, or more frequently if events or changes in circumstances indicate that IPR&D assets may be impaired.

The Company evaluated the Glemba IPR&D asset for potential impairment related to the discontinuation of the Glemba program. The Company concluded that the Glemba IPR&D asset was fully impaired, and a non-cash impairment charge of $11.8 million was recorded for the three months ended March 31, 2018. CDX-3379 is in Phase 2 development. The anti-KIT and TAM programs are in preclinical development.

As of March 31, 2018, none of the remaining IPR&D assets had reached technological feasibility nor did any have alternative future uses. Due to the nature of IPR&D projects, the Company may experience future delays or failures to obtain regulatory approvals to conduct clinical trials, failures of such clinical trials or other failures to achieve a commercially viable product, and as a result, may recognize further impairment losses in the future.

*Goodwill*

The changes in the carrying amount of goodwill for the three months ended March 31, 2018 were as follows:

| | Goodwill (In thousands) |
|---|---|
| Balance at December 31, 2017 | $ 90,976 |
| Goodwill Impairment | (90,976) |
| Balance at March 31, 2018 | $ — |

The Company evaluated goodwill for potential impairment due to the METRIC failure. The carrying amount of the Company was compared to the Company's fair value. The Company's fair value assessment reflected a number of significant management assumptions and estimates including the Company's probability forecasts for pipeline assets, income taxes, capital expenditures and changes in working capital requirements. Changes in these assumptions and/or discount rates could materially impact the Company's conclusions. Through this assessment, it was determined that the carrying amount of the Company exceeded its fair value by over $91.0 million. As such, the full goodwill asset was considered impaired and a charge of $91.0 million was recorded during the three months ended March 31, 2018.

**(7) Other Long-Term Liabilities**

Other long-term liabilities include the following:

| | March 31, 2018 | December 31, 2017 |
|---|---|---|
| | (In thousands) | |
| Net Deferred Tax Liabilities Related to IPR&D (Note 12) | $ 3,007 | $ 3,772 |
| Deferred Income From Sale of Tax Benefits | 6,402 | 6,756 |
| Other | 1,267 | 1,344 |
| Contingent Milestones (Note 4) | 29,800 | 43,400 |
| Deferred Revenue (Note 11) | 1,413 | 2,813 |
| Total | 41,889 | 58,085 |
| Less Current Portion | (8,607) | (6,566) |
| Long-Term Portion | $ 33,282 | $ 51,519 |

In November 2015, December 2014, January 2014 and January 2013, the Company received approval from the New Jersey Economic Development Authority and agreed to sell New Jersey tax benefits of $9.8 million, $1.9 million, $1.1 million and $0.8 million to an independent third party for $9.2 million, $1.8 million, $1.0 million and $0.8 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 three months ended March 31, 2018 and 2017, the Company recorded $0.4 million and $0.5 million to other income related to the sale of these tax benefits, respectively.

**(8) Stockholders' Equity**

In May 2016, the Company entered into an agreement with Cantor Fitzgerald & Co. ("Cantor") to allow the Company to issue and sell shares of its common stock having an aggregate offering price of up to $60.0 million from time to time through Cantor, acting as agent. In November 2017, the Company filed a prospectus supplement registering the offer and sale of shares of common stock of up to an additional $75.0 million under the agreement with Cantor. During the three months ended March 31, 2018, the Company issued 4,692,024 shares of common stock under this controlled equity offering sales agreement with Cantor resulting in net

proceeds of $11.7 million after deducting commission and offering expenses. At March 31, 2018, the Company had $55.5 million remaining in aggregate gross offering price available under the Cantor agreement.

**(9) Stock-Based Compensation**

A summary of stock option activity for the three months ended March 31, 2018 is as follows:

| | Shares | Weighted Average Exercise Price Per Share | Weighted Average Remaining Contractual Term (In Years) |
|---|---|---|---|
| Options Outstanding at December 31, 2017 | 10,856,212 | $ 9.40 | 6.1 |
| Granted | 18,000 | $ 2.82 | |
| Exercised | (104,500) | $ 2.80 | |
| Canceled | (1,313,031) | $ 8.83 | |
| Options Outstanding at March 31, 2018 | 9,456,681 | $ 9.55 | 6.5 |
| Options Vested and Expected to Vest at March 31, 2018 | 9,313,514 | $ 9.62 | 6.5 |
| Options Exercisable at March 31, 2018 | 5,827,235 | $ 11.85 | 5.2 |
| Shares Available for Grant Under the 2008 Plan | 8,879,518 | | |

The weighted average grant-date fair value of stock options granted during the three-month period ended March 31, 2018 was $1.86. Stock-based compensation expense for the three months ended March 31, 2018 and 2017 was recorded as follows:

| | Three months ended March 31, | |
|---|---|---|
| | 2018 | 2017 |
| | (In thousands) | |
| Research and development | $ 1,311 | $ 1,893 |
| General and administrative | 1,177 | 1,646 |
| Total stock-based compensation expense | $ 2,488 | $ 3,539 |

The fair values of employee and director stock options granted during the three months ended March 31, 2018 and 2017 were valued using the Black-Scholes option pricing model with the following assumptions:

| | Three months ended March 31, | |
|---|---|---|
| | 2018 | 2017 |
| Expected stock price volatility | 73% | 76 - 77% |
| Expected option term | 6.0 Years | 6.0 Years |
| Risk-free interest rate | 2.8% | 2.3% |
| Expected dividend yield | None | None |

**(10) Accumulated Other Comprehensive Income**

The changes in accumulated other comprehensive income, which is reported as a component of stockholders' equity, for the three months ended March 31, 2018 are summarized below:

| | Unrealized Gain (Loss) on Marketable Securities | Foreign Currency Items | Total |
|---|---|---|---|
| | | (In thousands) | |
| Balance at December 31, 2017 | $ (32) | $ 2,596 | $ 2,564 |
| Other comprehensive loss | (5) | — | (5) |
| Balance at March 31, 2018 | $ (37) | $ 2,596 | $ 2,559 |

No amounts were reclassified out of accumulated other comprehensive income during the three months ended March 31, 2018.

**(11) Revenue**

On January 1, 2018, the Company adopted a new revenue accounting standard, " *Revenue from Contracts with Customers* " *(ASC 606)* . Upon adoption using the modified retrospective application, the Company recognized a $1.3 million decrease to accumulated deficit, a $0.8 million decrease in deferred revenue and $0.5 million increase in accounts receivable due to the cumulative impact of adopting *ASC 606* . This impact was driven by the acceleration of revenue using a percentage-of-completion method of accounting under *ASC 606* for an open contract that had previously been accounted for using the Contingency Adjusted Performance Model ("CAPM") under previous guidance.

Results for reporting periods beginning after January 1, 2018 are presented under *ASC 606* while prior period amounts were not adjusted and continue to be reported in accordance with historic accounting under previous guidance. There was not a material impact to revenues as a result of applying *ASC 606* for the three months ended March 31, 2018, and there have not been significant changes to the Company's business processes, systems or internal controls as a result of adopting the new standard. The Company expects revenue recognition to remain largely unchanged under the new standard.

*Revenue Recognition*

Revenues are recognized when performance obligations under agreements or contracts are satisfied, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those services.

The Company determines revenue recognition through the following steps:

- Identification of the contract, or contracts, with a customer;
- Identification of the performance obligations in the contract;
- Determination of the transaction price;
- Allocation of the transaction price to the performance obligations in the contract; and
- Recognition of revenue when, or as, the Company satisfies a performance obligation.

Revenue for the Company has historically been derived from biopharmaceutical product development agreements with collaborative partners for the research and development of therapeutic drug candidates. The terms of the agreements may include nonrefundable signing and licensing fees, funding for research, development and manufacturing, milestone payments and royalties on any product sales derived from collaborations. The Company assesses the multiple obligations typically within product development contracts to determine the distinct performance obligations and how to allocate the arrangement consideration to each distinct performance obligation.

Under product development agreements, revenue is generally recognized using a cost-to-cost measure of progress. Revenue is recognized based on the costs incurred to date as a percentage of the total estimated costs to fulfill the contract. Incurred cost represents work performed, which corresponds with, and thereby best depicts, the transfer of control to the customer. Due to the nature of the work performed in these arrangements, the estimation of cost at completion is complex, subject to many variables, such as expected clinical trail costs, and requires significant judgements. Circumstances can arise that change original estimates of costs or progress toward completion. Any revisions to estimates are reflected in revenue on a cumulative catch-up basis in the period in which the change in circumstances became known.

Revenue for the Company is also derived from manufacturing and research and development arrangements. The Company owns and operates a cGMP manufacturing facility in Fall River, Massachusetts, to produce drug substance for its current and planned early-stage clinical trials. In order to utilize excess capacity, the Company has, from time to time, entered into contract manufacturing and research and development arrangements in which services are provided on a time-and-material basis or at a negotiated fixed-price. Revenue from time-and-material contracts is generally recognized on an output basis as labor hours and/or direct expenses are incurred. Under fixed-price contracts, revenue is generally recognized on an output basis as progress is made toward completion of the performance obligations using surveys of performance completed to date.

*Contract Assets and Liabilities*

The Company classifies the right to consideration in exchange for products or services transferred to a client as either a receivable or a contract asset. A receivable is a right to consideration that is unconditional as compared to a contract asset which is a right to consideration that is conditional upon factors other than the passage of time. At January 1, 2018 and March 31, 2018, the Company's right to consideration under all contracts was considered unconditional, and as such, there were no recorded contract assets.

The Company's contract liabilities result from arrangements where the Company has received payment in advance of performance under the contract. These amounts are included as deferred revenue within other long-term liabilities and current portion of long term liabilities on the condensed consolidated balance sheets. Revenue recognized from contract liabilities as of January 1, 2018 during the three months ended March 31, 2018 was $0.6 million. Revenue expected to be recognized in the future from contract liabilities as performance obligations are satisfied are not expected to be material.

*Product Development and Licensing Revenue*

The Company's primary product development and licensing revenue is associated with a clinical collaboration agreement with BMS. This agreement was entered into in 2014 and its purpose is to evaluate the safety, tolerability and preliminary efficacy of varlilumab and Opdivo ®, BMS's PD-1 immune checkpoint inhibitor, in a Phase 1/2 study. Under this agreement, BMS made an upfront payment to Celldex of $5.0 million and provides funding for 50% of the external costs incurred by the Company in connection with the clinical trial. The Company recorded $0.9 million in revenue related to this agreement during the three months ended March 31, 2018.

*Contract and Grants Revenue*

In 2017, the Company entered into fixed-fee manufacturing and research and development arrangements with both the International AIDS Vaccine Initiative (IAVI) and Frontier Biotechnologies, Inc (Frontier). The Company recognized $2.3 million and $0.0 million in revenue under these agreements during the three months ended March 31, 2018 and 2017, respectively.

In 2013, the Company entered into an agreement, as amended, with Rockefeller University pursuant to which the Company performs manufacturing and research and development services for Rockefeller University. The Company recognized $0.7 million and $0.8 million in revenue for labor hours and direct costs incurred related to the Rockefeller University agreement during the three months ended March 31, 2018 and 2017, respectively.

**(12) Income Taxes**

On December 22, 2017, the Tax Cuts and Jobs Act ("TCJA") was enacted and led to significant changes to U.S. tax law. Also on December 22, 2017, the SEC staff issued SAB 118, allowing companies to record the effects of the TCJA on a provisional basis during a measurement period not to extend beyond one year of the enactment date. SAB 118 was codified into ASC 740 by ASU 2018-05.

The Company recognized an income tax benefit of $19.1 million related to implementing applicable provisions of the TCJA during the year ended December 31, 2017. In accordance with SAB 118, the Company considered this adjustment to be a provisional amount based on the Company's best estimates at December 31, 2017. During the three months ended March 31, 2018, there was no further information or change in estimates related to the provisional amount recognized during the year ended December 31, 2017. However, updated guidance, interpretations or assumptions could lead the Company to make further adjustments to income tax benefit (provision) in the future. The Company expects its accounting for the tax effects of the TCJA to be completed in 2018.

The Company has evaluated the positive and negative evidence bearing upon the realizability of its net deferred tax assets and considered its history of losses, ultimately concluding that it is "more likely than not" that the Company will not recognize the benefits of federal, state and foreign deferred tax assets and, as such, has maintained a full valuation allowance on its deferred tax assets as of March 31, 2018 and December 31, 2017.

A net deferred tax liability of $3.0 million and $3.8 million existed at March 31, 2018 and December 31, 2017, respectively, related to the temporary differences associated with the IPR&D intangible assets acquired in previous business combinations and not deductible for tax purposes. During the quarter ended March 31, 2018, a $0.8 million non-cash income tax benefit was recorded related to impaired Glemba IPR&D assets

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

**(13) 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:

| | Three Months Ended March 31, | |
|---|---|---|
| | 2018 | 2017 |
| Stock Options | 9,456,681 | 10,159,130 |
| Restricted stock | 96,668 | 50,000 |
| | 9,553,349 | 10,209,130 |

**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," "target," "potential" and other 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 our 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 liquidity needs, on terms acceptable to us, or at all. If we are unable to raise the funds necessary to meet our liquidity needs, we may have to delay or discontinue the development of one or more programs, discontinue or delay ongoing 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 negotiate strategic partnerships, where appropriate, for our program assets;
- our ability to manage multiple clinical trials for a variety of drug candidates at different stages of development;
- the cost, timing, scope and results of ongoing preclinical and clinical testing;
- the cost, timing and uncertainty of obtaining regulatory approvals for our drug candidates;
- the availability, cost, delivery and quality of clinical management services provided by our clinical research organization partners;
- 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;
- our ability to develop and commercialize products before competitors that are superior to the alternatives developed by such competitors;
- our ability to develop technological capabilities, including identification of novel and clinically important targets, exploiting our existing technology platforms to develop new drug candidates and expand our focus to broader markets for our existing targeted immunotherapeutics;
- our ability to maintain compliance with applicable NASDAQ listing standards for continued listing of our common stock on the NASDAQ Global Market;
- our ability to realize the anticipated benefits and cost-savings from the restructuring we announced in April 2018;
- our ability to realize the anticipated benefits from the acquisition of Kolltan and to operate the combined business efficiently;

- our ability to protect our intellectual property rights, including the ability to successfully defend patent oppositions filed against a European patent related to technology we use in varlilumab, and our ability to avoid intellectual property litigation, which can be costly and divert management time and attention; and

- the risk factors set forth elsewhere in this quarterly report on Form 10-Q 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, 2017 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 immunotherapies and other targeted biologics. Our drug candidates are derived from a broad set of complementary technologies which have the ability to engage the human immune system and/or directly inhibit tumors to treat specific types of cancer or other diseases. They are aimed at addressing market opportunities for which we believe current therapies are inadequate or non-existent.

In April 2018, we announced that that our randomized, Phase 2b METRIC Study of glembatumumab vedotin compared to Xeloda ® (capecitabine) in patients with metastatic triple-negative breast cancers that overexpress gpNMB failed to meet its primary endpoint of improving progression-free survival (PFS). We stated that based on this result, we would prioritize our pipeline and evaluate our operational and workforce needs to extend our financial resources and direct them to continued pipeline advancement. Progress on the pipeline prioritization initiative is reflected below.

We are focusing our efforts and resources on the continued research and development of:

- CDX-1140, an agonist human monoclonal antibody targeted to CD40, a key activator of immune response, currently in a Phase 1 dose-escalation study in multiple types of solid tumors;
- CDX-3379, a human monoclonal antibody designed to block the activity of ErbB3 (HER3) currently in an early Phase 2 study in advanced head and neck squamous cell cancer in combination with Erbitux ® ;
- CDX-301, a dendritic cell growth factor currently being evaluated in an investigator-initiated pilot study and planned for combination study with CDX-1140; and
- Varlilumab, an immune modulating antibody targeting CD27 designed to enhance a patient's immune response against cancer that is being studied in multiple investigator initiated research studies and is currently completing a Phase 1/2 study across multiple solid tumors in combination with Opdivo ® . We are conducting the study in collaboration with Bristol-Myers Squibb Company (BMS) and plan to present data at various medical meetings in 2018, including in an oral presentation at the 2018 ASCO Annual Meeting in June. We intend to explore varlilumab externally through several investigator-initiated studies and internally through inclusion in combination studies.

To conserve resources, we are discontinuing development of:

- Glembatumumab vedotin, a targeted antibody-drug conjugate (ADC), across all indications, as previously disclosed;
- CDX-014, an ADC (which are typically more costly to develop than other therapeutics), in early Phase 1 development in renal cell and clear cell ovarian carcinomas; and
- CDX-1401, an NY-ESO-1-antibody fusion protein, that was being explored in investigator-sponsored and collaborative studies.

We also routinely work with external parties to collaboratively advance our drug candidates. In addition to Celldex-led studies, we also have an Investigator Initiated Research (IIR) program with four studies ongoing with our prioritized drug candidates and additional studies currently under consideration.

Our goal is to build a fully integrated, commercial-stage biopharmaceutical company that develops important therapies for patients with unmet medical needs. We believe 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. Currently, all programs are fully owned by Celldex.

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 drug candidate. It is not unusual for the clinical development of these types of drug candidates to each take five years or more, and for total development costs to exceed $100 million for each drug candidate. We estimate that clinical trials of the type we generally conduct are typically completed over the following timelines:

| 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 drug candidate.

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

An element of our business strategy is to pursue the discovery, research and development of a broad portfolio of drug candidates. This is intended to allow us to diversify the risks associated with our research and development expenditures. To the extent we are unable to maintain a broad range of drug candidates, our dependence on the success of one or a few drug candidates increases.

Regulatory approval is required before we can market our drug 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 are 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 drug candidates. In the event that third parties take over the clinical trial process for one of our drug 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, 2017, we incurred an aggregate of $470.9 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 three months ended March 31, 2018 and 2017. 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.

| | Three Months Ended March 31, 2018 | Three Months Ended March 31, 2017 |
|---|---|---|
| | (In thousands) | |
| CDX-1140 | $ 932 | $ 2,945 |
| CDX-3379 | 678 | 1,385 |
| CDX-301 | 525 | 396 |
| Varlilumab | 2,510 | 4,892 |
| Anti-KIT Program | 1,686 | 1,376 |
| TAM Program | 1,692 | 1,046 |
| Glembatumumab vedotin | 8,921 | 8,838 |
| CDX-014 | 744 | 618 |
| CDX-1401 | 280 | 205 |
| Other Programs | 3,907 | 4,092 |
| Total R&D Expense | $ 21,875 | $ 25,793 |

**Clinical Development Programs**

*CDX-1140*

CDX-1140 is a fully human agonist monoclonal antibody targeted to CD40, a key activator of immune response, which is found on dendritic cells, macrophages and B cells and is also expressed on many cancer cells. Potent CD40 agonist antibodies have shown encouraging results in early clinical studies; however, systemic toxicity associated with broad CD40 activation has limited their dosing. CDX-1140 has unique properties relative to other CD40 agonist antibodies: potent agonist activity is independent of Fc receptor interaction, contributing to more consistent, controlled immune activation; CD40L binding is not blocked, leading to potential synergistic effects of agonist activity near activated T cells in lymph nodes and tumors; and the antibody does not promote cytokine production in whole blood assays. CDX-1140 has shown direct anti-tumor activity in preclinical models of lymphoma. Preclinical studies of CDX-1140 clearly demonstrate strong immune activation effects and low systemic toxicity and support the design of the Phase 1 study to rapidly identify the dose for characterizing single-agent and combination activity.

We initiated a Phase 1 study of CDX-1140 in November 2017. This study, which is expected to enroll up to approximately 105 patients with recurrent, locally advanced or metastatic solid tumors, is designed to determine the maximum tolerated dose, or MTD, during a dose-escalation phase (0.01 to 3.0 mg/kg once every four weeks until confirmed progression or intolerance) and to recommend a dose level for further study in a subsequent expansion phase. The expansion is designed to further evaluate the tolerability and biologic effects of selected dose(s) of CDX-1140 in specific tumor types. Secondary objectives include assessments of safety and tolerability, pharmacodynamics, pharmacokinetics, immunogenicity and additional measures of anti-tumor activity, including clinical benefit rate. We believe that the potential for CDX-1140 will be best defined in combination studies with other immunotherapies or conventional cancer treatments. We are currently exploring plans for potential combination arms with CDX-301 and varlilumab.

*CDX-3379*

CDX-3379 is a human monoclonal antibody with half-life extension designed to block the activity of ErbB3 (HER3). We believe ErbB3 may be an important receptor regulating cancer cell growth and survival as well as resistance to targeted therapies and is expressed in many cancers, including head and neck, thyroid, breast, lung and gastric cancers, as well as melanoma. We believe the proposed mechanism of action for CDX-3379 sets it apart from other drugs in development in this class due to its ability to block both

ligand-independent and ligand-dependent ErbB3 signaling by binding to a unique epitope. It has a favorable pharmacologic profile, including a longer half-life and slower clearance relative to other drug candidates in this class. We believe CDX-3379 also has potential to enhance anti-tumor activity and/or overcome resistance in combination with other targeted and cytotoxic therapies to directly kill tumor cells. Tumor cell death and the ensuing release of new tumor antigens has the potential to serve as a focus for combination therapy with immuno-oncology approaches, even in refractory patients. CDX-3379 has been evaluated in three Phase 1 studies for the treatment of multiple solid tumors that express ErbB3 and is currently being evaluated is a Phase 2 study in combination with Erbitux in Erbitux-resistant, advanced head and neck squamous cell carcinoma.

A Phase 1a/1b study of CDX-3379 was conducted in solid tumors. The study included a single-agent, dose-escalation portion and combination expansion cohorts. The single-agent, dose-escalation portion of the study did not identify an MTD, and there were no dose limiting toxicities. Four combination arms across multiple tumor types were added to evaluate CDX-3379 with several drugs that target EGFR, HER2 or BRAF. They include combinations with Erbitux ® (n=16), Tarceva ® (n=8), Zelboraf ® (n=9) and Herceptin ® (n=10). Patients had advanced disease and were generally heavily pretreated. Across the combination arms, the most frequent adverse events were diarrhea, nausea, rash and fatigue. Objective responses were observed in the Erbitux and Zelboraf combination arms. In the Erbitux arm, there was one durable complete response in a patient with head and neck cancer, who had been previously treated with Erbitux and was refractory. In the Zelboraf arm, there were two partial responses in patients who had lung cancer, one of whom had been previously treated with Tafinlar ® and was considered refractory, as well as a single timepoint partial response in a patient with thyroid cancer. Initial data were presented at the 2016 ASCO Annual Meeting.

In April 2018, results from a window-of-opportunity study evaluating the effect of CDX-3379 on potential biomarkers in patients with head and neck squamous cell carcinoma (HNSCC) were presented at the American Association for Cancer Research (AACR) Annual Meeting. The study enrolled 12 patients with newly diagnosed HNSCC who received two doses of CDX-3379, at a two-week interval prior to tumor resection. CDX-3379 reduced phosphorylated ErbB3 (pErbB3) levels in 83% (10/12) of patient samples, with greater than or equal to 50% decreases in 58% of patients (7/12), which met the primary study objective. Stable disease was observed in 92% (11/12) of patients prior to surgery, and a patient with HPV-negative disease experienced significant tumor shrinkage (92% in primary tumor; 26% in metastatic lesion). CDX-3379 was well-tolerated, and no treatment-related adverse events were observed.

Preclinical data from the combination of CDX-3379 and Erbitux in xenograft models of head and neck squamous cell carcinoma were also presented at the AACR Annual Meeting in April 2018. Combining CDX-3379 and Erbitux inhibited tumor growth more potently than Erbitux alone. Mechanistic studies demonstrated a reduction of PD-L1 expression from the combination.

We have initiated an open-label Phase 2 study in combination with Erbitux in approximately 30 patients with human papillomavirus (HPV) negative, Erbitux -resistant, advanced head and neck squamous cell carcinoma who have previously been treated with an anti-PD1 checkpoint inhibitor, a population with limited options and a particularly poor prognosis. We opened the study to enrollment in November 2017. The primary objective of the study is objective response rate. Secondary objectives include assessments of clinical benefit response (CBR), duration of response (DOR), progression-free survival (PFS) and overall survival (OS), and safety and pharmacokinetics associated with the combination.

*Varlilumab*

Varlilumab is a fully human agonist monoclonal antibody that binds to and activates CD27, a critical co-stimulatory molecule in the immune activation cascade. We believe varlilumab works primarily by stimulating T cells, an important component of a person's immune system, to attack cancer cells. Restricted expression and regulation of CD27 enables varlilumab specifically to activate T cells, resulting in an enhanced immune response with the potential for a favorable safety profile. In preclinical studies, varlilumab has been shown to directly kill or inhibit the growth of CD27 expressing lymphomas and leukemias in *in vitro* and *in vivo* models. We have entered into license agreements with the University of Southampton, UK for intellectual property to use anti-CD27 antibodies and with Medarex (acquired by Bristol-Myers Squibb Company, or BMS) for access to the UltiMab technology to develop and commercialize human antibodies to CD27. Varlilumab was initially studied as a single-agent to establish a safety profile and assess immunologic and clinical activity in patients with cancer, but we believe the greatest opportunity for varlilumab is as an immune activator in combination with other agents. Currently, we are focusing our efforts on a Phase 1/2 clinical trial being conducted in collaboration with BMS and their PD-1 immune checkpoint inhibitor, Opdivo. Varlilumab is also being studied in ongoing and planned investigator-sponsored and collaborative studies, and we are evaluating the inclusion of varlilumab in additional Celldex-sponsored combination studies.

**Single-Agent Phase 1 Study:** In an open-label Phase 1 study of varlilumab in patients with selected malignant solid tumors or hematologic cancers, varlilumab demonstrated an acceptable safety profile and induced immunologic activity in patients that is consistent with both its proposed mechanism of action and data in preclinical models. A total of 90 patients received varlilumab in the

study at multiple clinical sites in the U.S. In both the solid tumor and hematologic dose escalations, the pre-specified maximum dose level (10 mg/kg) was reached without identification of an MTD. The majority of adverse events, or AEs, related to treatment have been mild to moderate (Grade 1/2) in severity, and no significant immune-mediated adverse events typically associated with checkpoint blockade have been observed. Durable, multi-year clinical benefit was demonstrated in select patients without additional anti-cancer therapy. Final results from the study in patients with solid tumors were published in the *Journal of Clinical Oncology* in April 2017.

**Phase 1/2 Varlilumab/Opdivo Combination Study:** In 2014, we entered into a clinical trial collaboration with BMS to evaluate the safety, tolerability and preliminary efficacy of varlilumab and Opdivo, BMS' 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 us of $5.0 million, and the companies amended the terms of our existing license agreement with Medarex (acquired by BMS) related to our CD27 program, whereby certain future milestone payments were waived and future royalty rates were reduced that may have been due from us to Medarex. In return, BMS was granted a time-limited right of first negotiation if we wish 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 we will be responsible for conducting the Phase 1/2 study.

The Phase 1/2 study was initiated in January 2015 and is being conducted in adult patients with multiple solid tumors to assess the safety and tolerability of varlilumab at varying doses when administered with Opdivo, followed by a Phase 2 expansion to evaluate the activity of the combination in disease specific cohorts.

Data (n=36) from the Phase 1 dose-escalation portion of the study were presented in an oral presentation at the 2017 ASCO Annual Meeting. The combination was well tolerated at all varlilumab dose levels tested without any evidence of increased autoimmunity or inappropriate immune activation. Marked changes in the tumor microenvironment, which have been shown to correlate with a greater magnitude of treatment effect from checkpoint inhibitors in other clinical studies, and additional evidence of immune activity were observed.

The Phase 2 portion of the study opened to enrollment in April 2016 and completed enrollment in January 2018 with cohorts in colorectal cancer (n=21), ovarian cancer (n=58), head and neck squamous cell carcinoma (n=24), renal cell carcinoma (n=14) and glioblastoma (n=22). The primary objective of the Phase 2 cohorts is objective response rate, or ORR, except glioblastoma, where the primary objective is the rate of 12-month OS. Data from the colorectal and ovarian cancer cohorts will be presented in an oral presentation at the 2018 ASCO Annual Meeting, and data from remaining cohorts will be presented at future medical meetings in 2018.

We intend to explore varlilumab externally through several investigator-initiated studies and internally through inclusion in combination studies.

*CDX-301*

CDX-301, a recombinant FMS-like tyrosine kinase 3 ligand, or Flt3L, is a hematopoietic cytokine that uniquely expands dendritic cells and hematopoietic stem cells, and in combination with other agents may potentiate anti-tumor responses. Depending on the setting, cells expanded by CDX-301 promote either enhanced or permissive immunity. CDX-301 is in clinical development for multiple cancers, in combination with treatments that release tumor antigens, such as radiation therapy. We licensed CDX-301 from Amgen Inc. and believe CDX-301 may hold significant opportunity for synergistic development in combination with other proprietary molecules in our portfolio, as well as with approved or investigational therapies for the treatment of cancer.

A Phase 1 study of CDX-301 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 has an acceptable safety profile to date and can mobilize dendritic cell and hematopoietic stem cell populations in healthy volunteers. The study was published in the journal Bone Marrow Transplantation in 2015.

CDX-301 is being studied in ongoing and planned investigator-sponsored and collaborative studies and is planned for combination study with CDX-1140 in the ongoing Phase 1 trial of CDX-1140. Development of CDX-301 in combination with glembatumumab vedotin in metastatic melanoma has been discontinued as part of the pipeline prioritization conducted in April 2018.

*Glembatumumab vedotin*

On April 16, 2018, we announced that our randomized, Phase 2b METRIC Study of glembatumumab vedotin compared to Xeloda (capecitabine) in patients with metastatic triple-negative breast cancers that overexpress gpNMB failed to meet its primary endpoint, progression-free survival (PFS) as assessed by an independent, central reading of patient scans (Hazard ratio = 0.95; median PFS: glembatumumab vedotin 2.9 months vs. Xeloda 2.8 months; p=0.76). Based on these results, we also made the decision to discontinue the glembatumumab vedotin program across all indications. Study closure activities are in process and following completion of these activities, we do not expect to incur significant expenses related to spend for glembatumumab vedotin.

*CDX-014*

CDX-014 is a human monoclonal ADC that targets T cell immunoglobulin and mucin domain 1, or TIM-1, and uses Seattle Genetics' MMAE toxin and linker technology. CDX-014 was being studied in a Phase 1/2 trial in patients with both clear cell and papillary renal cell carcinoma and ovarian clear cell carcinoma. To conserve resources, as part of our pipeline prioritization conducted in April 2018, we are discontinuing development of CDX-014.

*CDX-1401*

CDX-1401 is an NY-ESO-1-antibody fusion protein for immunotherapy in multiple solid tumors. Its potential activity was being explored in investigator-sponsored and collaborative studies. To conserve resources, as part of our pipeline prioritization conducted in April 2018, we are discontinuing development of CDX-1401, including in collaborative studies.

**CRITICAL ACCOUNTING POLICIES**

See Note 3 to the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for information regarding newly adopted and recent accounting pronouncements. See also Note 2 to our financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2017 for a discussion of our critical accounting policies. There have been no material changes to such critical accounting policies except for the adoption of the updated revenue recognition standard on January 1, 2018. We believe our most critical accounting policies include accounting for business combinations, revenue recognition, intangible and long-lived assets, research and development expenses and stock-based compensation expense.

**RESULTS OF OPERATIONS**

***Three Months Ended March 31, 2018 Compared with Three Months Ended March 31, 2017***

| | Three Months Ended March 31, | | Increase/ (Decrease) | Increase/ (Decrease) |
|---|---|---|---|---|
| | 2018 | 2017 | $ | % |
| | (In thousands) | | | |
| Revenues: | | | | |
| Product Development and Licensing Agreements | $ 992 | $ 556 | $ 436 | 78% |
| Contracts and Grants | 3,076 | 978 | 2,098 | 215% |
| Total Revenue | $ 4,068 | $ 1,534 | $ 2,534 | 165% |
| Operating Expenses: | | | | |
| Research and Development | 21,875 | 25,793 | (3,918) | (15)% |
| General and Administrative | 5,593 | 7,229 | (1,636) | (23)% |
| Goodwill Impairment | 90,976 | — | 90,976 | n/a |
| Intangible Asset Impairment | 18,677 | — | 18,677 | n/a |
| (Gain)/Loss on Fair Value Remeasurement of Contingent Consideration | (13,600) | 3,400 | 17,000 | 500% |
| Amortization of Acquired Intangible Assets | 224 | 224 | — | —% |
| Total Operating Expense | 123,745 | 36,646 | 87,099 | 238% |
| Operating Loss | (119,677) | (35,112) | 84,565 | 241% |
| Investment and Other Income, Net | 780 | 851 | (71) | (8)% |
| Net Loss Before Income Tax Benefit | (118,897) | (34,261) | 84,636 | 247% |
| Income Tax Benefit | 765 | — | 765 | n/a |
| Net Loss | $ (118,132) | $ (34,261) | $ 83,871 | 245% |

*Net Loss*

The $83.9 million increase in net loss for the three months ended March 31, 2018, as compared to the three months ended March 31, 2017, was primarily the result of the non-cash charges related to fully impairing our goodwill asset and Glemba related intangible assets. This increase was partially offset by (i) gain on contingent consideration related to Glemba related milestones and discount rates and (ii) decreases in both research and development and general and administrative expenses.

*Revenue*

The $0.4 million increase in product development and licensing agreements revenue for the three months ended March 31, 2018, as compared to the three months ended March 31, 2017, was primarily due to an increase in reimbursable clinical trial expenses related to our BMS agreement. The $2.1 million increase in contracts and grants revenue for the three months ended March 31, 2018, as compared to the three months ended March 31, 2017, was primarily related to our contract manufacturing and research and development agreements with International AIDS Vaccine Initiative and Frontier Biotechnologies, Inc. signed in the second quarter of 2017.

*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 drug candidates as follows:

| | Three Months Ended March 31, | | Increase/ (Decrease) | |
|---|---|---|---|---|
| | 2018 | 2017 | $ | % |
| | (In thousands) | | | |
| Personnel | $ 9,057 | $ 10,023 | $ (966) | (10)% |
| Laboratory Supplies | 1,257 | 956 | 301 | 31% |
| Facility | 2,063 | 2,480 | (417) | (17)% |
| License Fees | 88 | 170 | (82) | (48)% |
| Product Development | 7,349 | 9,944 | (2,595) | (26)% |

Personnel expenses primarily include salary, benefits, stock-based compensation and payroll taxes. The $1.0 million decrease in personnel expenses for the three months ended March 31, 2018, as compared to the three months ended March 31, 2017, was primarily due to decreases in salaries expense and lower stock-based compensation expense. We expect personnel expenses to decrease over the next twelve months due to the restructuring the Company announced in April 2018.

Laboratory supplies expenses include laboratory materials and supplies, services, and other related expenses incurred in the development of our technology. The $0.3 million increase in laboratory supply expenses for the three months ended March 31, 2018, as compared to the three months ended March 31, 2017, was primarily due to higher laboratory materials and supplies purchases. We expect laboratory supplies expenses to decrease 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 $0.4 million decrease in facility expenses for the three months ended March 31, 2018, as compared to the three months ended March 31, 2017, was primarily due to lower depreciation expense of $0.3 million. 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. The $0.1 million decrease in license fee expenses for the three months ended March 31, 2018, as compared to the three months ended March 31, 2017, was due to the timing of certain development and/or regulatory milestones achieved by our drug candidates. We expect license fee expense to remain relatively consistent over the next twelve months, although there may be fluctuations on a quarterly basis.

Product development expenses include clinical investigator site fees, external trial monitoring costs, data accumulation costs, contracted research and outside clinical drug product manufacturing. The $2.6 million decrease in product development expenses for the three months ended March 31, 2018, as compared to the three months ended March 31, 2017, was primarily due to (i) lower clinical trial costs of $1.3 million related to varlilumab, Glemba and CDX-3379 programs and (ii) lower contract research costs of $0.8 million related to the CDX-1140, CDX-3379 and anti-KIT programs. The amount of product development expenses incurred over the next twelve months is expected to decrease due to the discontinuation of the Glemba and CDX-014 programs.

*General and Administrative Expense*

The $1.6 million decrease in general and administrative expenses for the three months ended March 31, 2018, as compared to the three months ended March 31, 2017, was primarily due to lower personnel expenses of $0.7 million, lower commercial planning costs of $0.4 million and lower legal, consulting and professional services expense of $0.3 million. The amount of general and administrative expenses incurred over the next twelve months is expected to decrease due to the restructuring the Company announced in April 2018.

*Gain on Fair Value Remeasurement of Contingent Consideration*

The $13.6 million gain on fair value remeasurement of contingent consideration for the three months ended March 31, 2018 was due to a reduction in fair value primarily due to updated assumptions for Glemba-related milestones and discount rates. See Note 4 to the financial statements included herein for a discussion of the contingent consideration that may be payable related to the Kolltan acquisition.

*Amortization Expense*

Amortization expense for the three months ended March 31, 2018 was consistent with the three months ended March 31, 2017. The remaining balance of our intangible assets subject to amortization was fully impaired for the three months ended March 31, 2018 due to the discontinuation of the Glemba program.

*Investment and Other Income, Net*

The $0.1 million decrease in investment and other income, net for the three months ended March 31, 2018, as compared to the three months ended March 31, 2017, was primarily due to lower levels of cash and investment balances, partially offset by higher interest rates on fixed income investments. We anticipate investment income to decrease over the next twelve months due to lower levels of cash and investment balances.

**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 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; and 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 and payments received for contract manufacturing and research and development services provided by us. The timing of any new contract manufacturing and research and development agreements, 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 March 31, 2018, our principal sources of liquidity consisted of cash, cash equivalents and marketable securities of $123.2 million. We have had recurring losses and incurred a loss of $118.1 million for the three months ended March 31, 2018. Net cash used in operations for the three months ended March 31, 2018 was $28.0 million. We believe that the cash, cash equivalents and marketable securities at March 31, 2018, combined with the anticipated proceeds from future sales of our common stock under the Cantor agreement, are sufficient to meet estimated working capital requirements and fund planned operations through 2020. This could be impacted if we elected to pay Kolltan contingent milestones, if any, in cash.

During the next twelve months, we will take further steps to raise additional capital to meet our liquidity needs. Our capital raising activities may include, but may not be limited to, one or more of the following: the licensing of drug candidates 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 may 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 financings 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. Our ability to continue funding our planned operations into and beyond twelve months from the issuance date is also dependent on the timing and manner of payment of future contingent milestones from the Kolltan acquisition, in the event that we achieve the drug candidate milestones related to those payments. We may decide to pay those milestone payments in cash, shares of our common stock or a combination thereof. If we are unable to raise the funds necessary to meet our liquidity needs, we may have to delay or discontinue the development of one or more programs, discontinue or delay ongoing or anticipated clinical trials, license out programs earlier than expected, raise funds at a significant discount or on other unfavorable terms, if at all, or sell all or a part of our business.

*Operating Activities*

Net cash used in operating activities was $28.0 million for the three months ended March 31, 2018 as compared to $35.3 million for the three months ended March 31, 2017. The decrease in net cash used in operating activities was primarily due to an increase in revenue and decreases in both general and administrative and research and development expenses. We expect that cash used in operating activities will decrease over the next twelve months primarily due to the restructuring we announced in April 2018, although there may be fluctuations on a quarterly basis.

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

*Investing Activities*

Net cash provided by investing activities was $15.5 million for the three months ended March 31, 2018 as compared to $22.4 million for the three months ended March 31, 2017. The decrease in net cash provided by investing activities was primarily due to net sales and maturities of marketable securities for the three months ended March 31, 2018 of $15.8 million as compared to $22.8 million for the three months ended March 31, 2017.

*Financing Activities*

Net cash provided by financing activities was $12.1 million for the three months ended March 31, 2018 as compared to $12.9 million for the three months ended March 31, 2017. Net proceeds from stock issuances pursuant to employee benefit plans were $0.4 million during the three months ended March 31, 2018 as compared to $0.1 million for the three months ended March 31, 2017.

In May 2016, we entered into an agreement with Cantor Fitzgerald & Co. ("Cantor") to allow us to issue and sell shares of our common stock having an aggregate offering price of up to $60.0 million from time to time through Cantor, acting as agent. In November 2017, we filed a prospectus supplement registering the offer and sale of shares of common stock of up to an additional $75.0 million under the agreement with Cantor. During the three months ended March 31, 2018, we issued 4,692,024 shares of common stock under this controlled equity offering sales agreement with Cantor resulting in net proceeds of $11.7 million after deducting commission and offering expenses. At March 31, 2018, we had $55.5 million remaining in aggregate gross offering price available under the Cantor agreement.

*Aggregate Contractual Obligations*

The disclosures relating to our contractual obligations reported in our Annual Report on Form 10-K for the year ended December 31, 2017 which was filed with the SEC on March 7, 2018 have not materially changed since we filed that report.

**OFF-BALANCE SHEET ARRANGEMENTS**

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules.

**Item 3. Quantitative and Qualitative Disclosures about Market 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 March 31, 2018 due to the short-term maturities of these instruments.

**Item 4. Controls and Procedures**

*Evaluation of Disclosure Controls and Procedures.*

As of March 31, 2018, 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 March 31, 2018. 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, 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 quarter ended March 31, 2018 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

Any investment in our business involves a high degree of risk. Before making an investment decision, you should carefully consider the information we include in this Quarterly Report on Form 10-Q, including the risks described below and our condensed financial statements and accompanying notes, and the additional information in the other reports we file with the Securities and Exchange Commission along with the risks described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017.

The risks described below and 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.

The risk factors set forth below contain material changes from, or additions to, the risk factors previously disclosed and included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017.

**Risks Related to Our Financial Condition and Capital Requirements**

***We currently have no product revenue and will need to raise capital to operate our business.***

To date, we have generated no product revenue and cannot predict when and if we will generate product revenue. We had an accumulated deficit of $812.5 million as of December 31, 2017. Until, and unless, we complete clinical trials and further development, and receive approval from the FDA and other regulatory authorities, for our drug candidates, we cannot sell our drugs and will not have product revenue. We expect to spend substantial funds to continue the research, development and testing of our products that are in the preclinical and clinical testing stages of development and to prepare to commercialize products in anticipation of FDA approval. Therefore, for the foreseeable future, we will have to fund all of our operations and development expenditures from cash on hand, equity or debt financings, licensing fees and grants. Following our recent announcement that our decision to discontinue the glembatumumab vedotin program across all indications after our Phase 2b METRIC Study of glembatumumab vedotin failed to meet its primary endpoint, our stock price has declined significantly, which may negatively affect our ability to raise additional capital. Additional financing will be required to meet our liquidity needs. If we do not succeed in raising additional funds on acceptable terms, we might not be able to complete planned preclinical and clinical trials or obtain approval of any drug candidates from the FDA and other regulatory authorities. In addition, we could be forced to discontinue product development, reduce or forego sales and marketing efforts, forego attractive business opportunities or curtail operations. Any additional sources of financing could involve the issuance of our equity securities, which would have a dilutive effect on our stockholders. No assurance can be given that additional financing will be available to us when needed on acceptable terms, or at all.

***As a result of our recent stock price decline, we may not be able to maintain compliance with the minimum bid price requirement of $1.00 per share for continued listing on the NASDAQ Global Market. If we fail to continue to meet all applicable Nasdaq Global Market requirements and Nasdaq determines to delist our common stock, the delisting could adversely affect the market liquidity of our common stock and the market price of our common stock could decrease.***

Our common stock is listed on The NASDAQ Global Market. In order to maintain our listing, we must meet minimum financial and other requirements, including the minimum bid price requirement of $1.00 per share for continued listing, as set forth in Nasdaq Listing Rule 5550(a)(2). Since April 16, 2018, the closing price for our stock has been below $1.00 per share. If the closing bid price of our common stock were to continue to be below $1.00 per share for 30 consecutive trading days or we do not meet other NASDAQ listing requirements, we would fail to be in compliance with NASDAQ listing standards. There can be no assurance that we will continue to meet the minimum bid price requirement, or any other requirement in the future. If we fail to meet the minimum bid price requirement, The Nasdaq Stock Market LLC may initiate the delisting process with a notification letter. If we were to receive such a notification, we would be afforded a grace period of 180 calendar days to regain compliance with the minimum bid price requirement. In order to regain compliance, shares of our common stock would need to maintain a minimum closing bid price of at least $1.00 per share for a minimum of 10 consecutive trading days. In addition, we may be unable to meet other applicable Nasdaq listing requirements, including maintaining minimum levels of stockholders' equity or market values of our common stock in which case, our common stock could be delisted. The failure to maintain our listing on NASDAQ could have an adverse effect on the market price and liquidity of our shares of common stock. Without a Nasdaq listing, shareholders may have a difficult time getting a quote for the sale or purchase of our shares, the sale or purchase of our shares would likely be made more difficult, and the trading volume and liquidity of our shares could decline. Delisting from Nasdaq could also result in negative publicity and could make it more difficult for us to raise additional capital.

***We expect to incur future losses and we may never become profitable.***

We have incurred operating losses of $121.5 million, $132.9 million and $129.5 million during 2017, 2016 and 2015, respectively, and expect to incur an operating loss in 2018 and beyond. We believe that operating losses will continue in 2018 and beyond because we are planning to incur significant costs associated with the clinical development of our drug candidates. During the years ended December 31, 2017, 2016 and 2015, we incurred $21.1 million, $24.9 million and $36.3 million in clinical trial expense and $11.4 million, $18.3 million and $14.8 million in contract manufacturing expense. Our net losses have had and will continue to have an adverse effect on, among other things, our stockholders' equity, total assets and working capital. We expect that losses will fluctuate from quarter to quarter and year to year, and that such fluctuations may be substantial. We cannot predict when we will become profitable, if at all.

***We will need additional capital to fund our operations, including the development, manufacture and potential commercialization of our drug candidates. If we do not have or cannot raise additional capital when needed, we may be unable to develop and ultimately commercialize our drug candidates successfully.***

We expect to incur significant costs as we develop our drug candidates. As of March 31, 2018, we had cash, cash equivalents and marketable securities of $123.2 million. During the next twelve months and beyond, we will take further steps to raise additional capital to fund our liquidity needs. Our capital raising activities may include, but may not be limited to, one or more of the following:

- licensing of drug candidates with existing or new collaborative partners;
- possible business combinations;
- issuance of debt; or
- issuance of common stock or other securities via private placements or public offerings.

While we may 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 drug candidates under development. 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 the build-out of our commercial infrastructure and our commercial planning and preparation activities, discontinue or delay ongoing 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 stockholders may be subject to substantial dilution if we elect to pay future milestone consideration to the former Kolltan stockholders in shares of common stock. If we elect to pay future milestone consideration in cash we would likely need to raise additional capital.***

The merger agreement between us and Kolltan provides that in the event that certain specified preclinical and clinical development milestones related to Kolltan's development programs and/or Celldex's development programs and certain commercial milestones related to Kolltan's drug candidates are achieved, we will be required to pay Kolltan's former stockholders milestone payments of up to $172.5 million, which milestone payments may be made, at our sole election, in cash, in shares of our common stock or a combination of both, although we are required to maintain a certain percentage of the overall consideration paid in Celldex common stock to satisfy certain tax requirements under the merger agreement. We may require additional capital to fund any milestone payments in cash, depending on the facts and circumstances at the time such payments become due. If we elect to pay the milestones in shares of our common stock, our stockholders would experience substantial dilution.

***U.S. federal income tax reform could adversely affect us.***

On December 22, 2017, the Tax Cuts and Jobs Act ("TCJA") was enacted, leading to significant changes to U.S. tax law. Among other provisions, the TCJA lowered the U.S. federal corporate income tax rate from 35% to 21%, limited the deduction for net operating losses to 80% of taxable income while providing that net operating loss carryovers for years after 2017 will not expire, imposed a mandatory one-time transition tax on previously deferred foreign earnings and eliminated or reduced certain income tax deductions. The estimated impact of the TCJA is based on our management's current knowledge and assumptions, and recognized impacts could be materially different from current estimates based on our actual results and our further analysis of the new law. We have revalued our net deferred tax assets and liabilities at the newly enacted U.S. federal rate, and we recognized a tax benefit of

$19.1 million during the year ended December 31, 2017 related to the TCJA. We continue to examine the impact this tax reform legislation may have on our business.

***We have significant goodwill and IPR&D and impairment of goodwill and IPR&D may have a significant adverse impact on our future financial condition and results of operations.***

As of March 31, 2018, we had goodwill and IPR&D assets of approximately $48.7 million. These intangible assets are subject to an impairment analysis whenever an event or change in circumstances indicates the carrying amount of such an asset may not be recoverable. We test our goodwill and IPR&D for impairment annually, or more frequently if an event or change in circumstances indicates that the asset may be impaired. If an impairment is identified, we would be required to record an impairment charge with respect to the impaired asset to our consolidated statements of operations and comprehensive loss. A significant impairment charge could have a material negative impact on our financial condition and results of operations.

We will continue to evaluate our intangible assets for potential impairment in accordance with our accounting policies. If additional impairments are identified, we would be required to record an impairment charge with respect to the impaired asset to our consolidated statements of operations and comprehensive loss. A significant impairment charge could have a material negative impact on our financial condition and results of operations.

Events giving rise to impairment are difficult to predict and are an inherent risk in the pharmaceutical industry. Some of the potential risks that could result in impairment of our goodwill and IPR&D include negative clinical study results, adverse regulatory developments, delay or failure to obtain regulatory approval, additional development costs, changes in the manner of our use or development of our product candidates, competition, earlier than expected loss of exclusivity, pricing pressures, higher operating costs, changes in tax laws, prices that third parties are willing to pay for our IPR&D or similar assets in an arm's-length transaction being less than the carrying value of our IPR&D, and other market and economic environment changes or trends. For example, we recorded an impairment charge of $18.7 million during the three months ended March 31, 2018 related to the discontinuation of our glembatumumab vedotin development program. Events or changes in circumstances may lead to significant impairment charges on our goodwill and/or IPR&D in the future, which could materially adversely affect our financial condition and results of operations.

**Risks Related to Development and Regulatory Approval of Drug Candidates**

***Our long term success depends heavily on our ability to fund and complete the research and development activities and obtain regulatory approval for our program assets.***

We are particularly dependent on the future success of our drug candidates. Only a small minority of all research and development programs ultimately result in commercially successful drugs. Clinical failure can occur at any stage of clinical development. For example, in April 2018, we decided to discontinue the glembatumumab vedotin program across all indications after our Phase 2b METRIC Study of glembatumumab vedotin in patients with metastatic triple-negative breast cancers that overexpress gpNMB failed to meet its primary endpoint and in March 2016, we decided to discontinue ACT IV, a randomized Phase 3 clinical study of Rintega in patients with newly diagnosed EGFRvIII-positive glioblastoma, based on the determination by the independent Data Safety and Monitoring Board that continuation of the ACT IV study would not reach statistical significance for overall survival in patients with minimal residual disease, the primary endpoint of the study, because both the Rintega arm and the control arm were performing on par with each other. Clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical or preclinical trials. In addition, data obtained from trials are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a drug candidate.

We will need substantial additional financing to complete the development of our drug candidates. Further, even if we complete the development of any of our drug candidates and gain marketing approvals from the FDA and comparable foreign regulatory authorities in a timely manner, we cannot be sure that such drug candidate will be commercially successful in the pharmaceutical market. If the results of clinical trials, the anticipated or actual timing of marketing approvals, or the market acceptance of any drug candidate, if approved, do not meet the expectations of investors or public market analysts, the market price of our common stock would likely decline.

***We may enter into collaboration agreements for the licensing, development and ultimate commercialization of some of our drug candidates including, where appropriate, for our lead drug candidates. In such cases, we will depend greatly on our third-party collaborators to license, develop and commercialize such drug candidates, and they may not meet our expectations.***

We may enter into co-development and commercialization partnerships for our drug candidates where appropriate. The process of identifying collaborators and negotiating collaboration agreements for the licensing, development and ultimate commercialization of some of our drug candidates may cause delays and increased costs. We may not be able to enter into collaboration agreements on terms favorable to us or at all. Furthermore some of those agreements may give substantial responsibility over our drug candidates to the collaborator. Some collaborators may be unable or unwilling to devote sufficient resources to develop our drug candidates as their agreements require. They often face business risks similar to ours, and this could interfere with their efforts. Also, collaborators may choose to devote their resources to products that compete with ours. If a collaborator does not successfully develop any one of our products, we will need to find another collaborator to do so. The success of our search for a new collaborator will depend on our legal right to do so at the time and whether the product remains commercially viable.

If we enter into collaboration agreements for one or more of our lead drug candidates, the success of such drug candidates will depend in great part upon our and our collaborators' success in promoting them as superior to other treatment alternatives. We believe that our drug candidates can be proven to offer disease treatment with notable advantages over drugs in terms of patient compliance and effectiveness. However, there can be no assurance that we will be able to prove these advantages or that the advantages will be sufficient to support the successful commercialization of our drug candidates.

***Our drug candidates are subject to extensive regulatory scrutiny.***

All of our drug candidates are at various stages of development, and our activities and drug candidates are significantly regulated by a number of governmental entities, including the FDA in the United States and by comparable authorities in other countries. These entities regulate, among other things, the manufacture, testing, safety, effectiveness, labeling, documentation, advertising and sale of drugs and drug candidates. We or our partners must obtain regulatory approval for a drug candidate in all of these areas before we can commercialize any of our drug candidates. Product development within this regulatory framework takes a number of years and involves the expenditure of substantial resources. This process typically requires extensive preclinical and clinical testing, which may take longer or cost more than we anticipate, and may prove unsuccessful due to numerous factors. Many drug candidates that initially appear promising ultimately do not reach the market because they are found to be unsafe or ineffective when tested. Companies in the pharmaceutical, biotechnology and immunotherapeutic drug industries have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier trials. Our inability to commercialize a drug candidate would impair our ability to earn future revenues.

***If our drug candidates do not pass required tests for safety and effectiveness, we will not be able to obtain regulatory approval and derive commercial revenue from them.***

In order to succeed, we will need to obtain regulatory approval for our drug candidates. The FDA has not approved any of our drug candidates for sale to date. Our drug candidates are in various stages of preclinical and clinical testing. Preclinical tests are performed at an early stage of a product's development and provide information about a drug candidate's safety and effectiveness on laboratory animals. Preclinical tests can last years. If a product passes its preclinical tests satisfactorily and we determine that further development is warranted, we would file an IND application for the product with the FDA, and if the FDA gives its approval, we would begin Phase 1 clinical tests. Phase 1 testing generally lasts between 6 and 24 months. If Phase 1 test results are satisfactory and the FDA gives its approval, we can begin Phase 2 clinical tests. Phase 2 testing generally lasts between 6 and 36 months. If Phase 2 test results are satisfactory and the FDA gives its approval, we can begin Phase 3 pivotal studies. Phase 3 studies generally last between 12 and 48 months. Once clinical testing is completed and a BLA or NDA is filed with the FDA, it may take more than a year to receive FDA approval.

In all cases we must show that a drug candidate is both safe and effective before the FDA, or drug approval agencies of other countries where we intend to sell the product, will approve it for sale. Our research and testing programs must comply with drug approval requirements both in the United States and in other countries, since we are developing our lead drug candidates with the intention to, or could later decide to, commercialize them both in the U.S. and abroad. A product may fail for safety or effectiveness at any stage of the testing process. A major risk we face is the possibility that none of our products under development will come through the testing process to final approval for sale, with the result that we cannot derive any commercial revenue from them after investing significant amounts of capital in multiple stages of preclinical and clinical testing.

***Success in early clinical trials does not ensure that later clinical trials will be successful, as illustrated by the recent failure of our Phase 2b METRIC Study to reach its primary endpoint.***

The results of preclinical studies and early clinical trials may not be predictive of the results of later-stage clinical trials, and interim results of a clinical trial do not necessarily predict final results. In particular, we recently announced that our Phase 2b

METRIC Study failed to reach its primary endpoint. Data, our interpretation of data and results for our earlier clinical studies of our drug candidates do not ensure that we will achieve similar results in later stage trials. Preclinical and clinical data are susceptible to various interpretations and analyses, and many companies that have believed their drug candidates performed satisfactorily in preclinical studies and early-stage clinical trials have nonetheless failed to replicate such results in later-stage clinical trials and subsequently failed to obtain marketing approval. Drug candidates in later-stage clinical trials may fail to show the desired safety and efficacy despite having progressed through preclinical and initial clinical trials, even if certain analyses of primary or secondary endpoints in those early trials showed trends towards efficacy. Later-stage clinical trials with larger numbers of patients or longer durations of therapy may also reveal safety concerns that were not identified in earlier smaller or shorter trials. Our failure to demonstrate efficacy and safety data sufficient to support marketing approval for any of our drug candidates would substantially harm our business, prospectus, financial condition and results of operations.

***We may be unable to manage multiple late-stage clinical trials for a variety of drug candidates simultaneously.***

As our current clinical trials progress, we may need to manage multiple late-stage clinical trials simultaneously in order to continue developing all of our current products. The management of late-stage clinical trials is more complex and time consuming than early-stage trials. Typically, early-stage trials involve several hundred patients in no more than 10 to 30 clinical sites. Late-stage (Phase 3) trials may involve up to several thousand patients in up to several hundred clinical sites and may require facilities in several countries. Therefore, the project management required to supervise and control such an extensive program is substantially larger than early-stage programs. As the need for these resources is not known until some months before the trials begin, it is necessary to recruit large numbers of experienced and talented individuals very quickly. If the labor market does not allow this team to be recruited quickly, the sponsor is faced with a decision to delay the program or to initiate it with inadequate management resources. This may result in recruitment of inappropriate patients, inadequate monitoring of clinical investigators and inappropriate handling of data or data analysis. Consequently it is possible that conclusions of efficacy or safety may not be acceptable to permit filing of a BLA or NDA for any one of the above reasons or a combination of several.

***Product testing is critical to the success of our drug candidates but subject to delay or cancellation if we have difficulty enrolling patients.***

As our portfolio of drug candidates moves from preclinical testing to clinical testing, and then through progressively larger and more complex clinical trials, we will need to enroll an increasing number of patients with the appropriate characteristics. At times we have experienced difficulty enrolling patients, and we may experience more difficulty as the scale of our clinical testing program increases. The factors that affect our ability to enroll patients are largely uncontrollable and include principally the following:

- the nature of the clinical test;
- the size of the patient population;
- patients' willingness to receive a placebo or less effective treatment on the control arm of a clinical study;
- the distance between patients and clinical test sites; and
- the eligibility criteria for the trial.

If we cannot enroll patients as needed, our costs may increase, or we may be forced to delay or terminate testing for a product.

***We may have delays in completing our clinical trials, and we may not complete them at all.***

We have not completed the clinical trials necessary to obtain FDA approval to market any of our drug candidates in development. Clinical trials for any of our products in development may be delayed or terminated as a result of many factors, including the following:

- difficulty in enrolling patients in our clinical trials;
- patients failing to complete clinical trials due to dissatisfaction with the treatment, side effects or other reasons;
- failure by regulators to authorize us to commence a clinical trial;
- suspension or termination by regulators of clinical research for many reasons, including concerns about patient safety or failure of our contract manufacturers to comply with cGMP requirements;
- delays or failure to obtain clinical supply for our products necessary to conduct clinical trials from contract manufacturers, including commercial grade-clinical supply for our Phase 3 clinical trials;
- drug candidates demonstrating a lack of efficacy during clinical trials;
- inability to continue to fund clinical trials or to find a partner to fund the clinical trials;
- competition with ongoing clinical trials and scheduling conflicts with participating clinicians; and
- delays in completing data collection and analysis for clinical trials.

Any delay or failure to complete clinical trials and obtain FDA approval for our drug candidates could have a material adverse effect on our cost to develop and commercialize, and our ability to generate revenue from, a particular drug candidate.

***If serious adverse or unacceptable side effects are identified during the development of our drug candidates, we may need to abandon or limit our development of some of our drug candidates.***

If our drug candidates are associated with serious adverse events or undesirable side effects in clinical trials or have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow uses or subpopulations in which the serious adverse events, undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. In pharmaceutical development, many drugs that initially show promise in early-stage testing for treating cancer are later found to cause side effects that prevent further development of the drug. Currently marketed therapies for the treatment of cancer are generally limited to some extent by their toxicity. In addition some of our drug candidates would be chronic therapies or be used in pediatric populations, for which safety concerns may be particularly important. Use of our drug candidates as monotherapies may also result in adverse events consistent in nature with other marketed therapies. In addition, when used in combination with other marketed therapies, our drug candidates may exacerbate adverse events associated with the marketed therapy.

***We may expend our resources to pursue a particular drug candidate or indication and forgo the opportunity to capitalize on drug candidates or indications that may ultimately be more profitable or for which there is a greater likelihood of success.***

Because we have limited financial and managerial resources, we intend to focus on developing drug candidates for specific indications that we identify as most likely to succeed, in terms of both their potential for regulatory approval and commercialization. As a result, we may forego or delay pursuit of opportunities with other drug candidates or for other indications that may prove to have greater commercial potential.

Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. Our spending on current and future research and development programs and drug candidates for specific indications may not yield any commercially viable drug candidates. If we do not accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to the drug candidate.

***Any delay in obtaining regulatory approval would have an adverse impact on our ability to earn future revenues.***

It is possible that none of the drug candidates that we develop will obtain the regulatory approvals necessary for us to begin commercializing them. The time required to obtain FDA and other approvals is unpredictable but often can take years following the commencement of clinical trials, depending upon the nature of the drug candidate. Any analysis we perform of data from clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. Any delay or failure in obtaining required approvals could have a material adverse effect on our ability to generate revenues from the particular drug candidate including, but not limited to, loss of patent term during the approval period. Furthermore, if we, or our partners, do not reach the market with our products before our competitors offer products for the same or similar uses, or if we, or our partners, are not effective in marketing our products, our revenues from product sales, if any, will be reduced.

We face intense competition in our development activities. We face competition from many companies in the United States and abroad, including a number of large pharmaceutical companies, firms specialized in the development and production of vaccines, adjuvants and vaccine and immunotherapeutic delivery systems and major universities and research institutions.

Most of our competitors have substantially greater resources, more extensive experience in conducting preclinical studies and clinical testing and obtaining regulatory approvals for their products, greater operating experience, greater research and development and marketing capabilities and greater production capabilities than those of ours. These companies might succeed in obtaining regulatory approval for competitive products more rapidly than we can for our products, especially if we experience any delay in obtaining required regulatory approvals.

***We have many competitors in our field, and they may develop technologies that make ours obsolete.***

Biotechnology, pharmaceuticals and therapeutics are rapidly evolving fields in which scientific and technological developments are expected to continue at a rapid pace. We have many competitors in the U.S. and abroad. Our success depends upon our ability to develop and maintain a competitive position in the product categories and technologies on which we focus. Many of our competitors have greater capabilities, experience and financial resources than we do. Competition is intense and is expected to increase as new products enter the market and new technologies become available. Our competitors may:

- develop technologies and products that are more effective than ours, making ours obsolete or otherwise noncompetitive;
- obtain regulatory approval for products more rapidly or effectively than us; and
- obtain patent protection or other intellectual property rights that would block our ability to develop competitive products.

**Risks Related to Commercialization of Our Drug Candidates**

***We may face delays, difficulties or unanticipated costs in establishing sales, marketing and distribution capabilities or seeking a partnership for the commercialization of our drug candidates, even if regulatory approval is obtained.***

We may choose to build a commercial organization which we believe could provide us with the strategic options to either retain full economic rights to our drug candidates or seek favorable economic terms through advantageous commercial partnerships. As a result, we may have full responsibility for commercialization of one or more of our drug candidates if and when they are approved for sale. We currently lack sufficient marketing, sales and distribution capabilities to carry out this strategy. If any of our drug candidates are approved by the FDA, we will need a drug sales force with technical expertise prior to the commercialization of any of our drug candidates. We may not succeed in developing such sales and distribution capabilities, the cost of establishing such sales and distribution capabilities may exceed any product revenue, or our direct marketing and sales efforts may be unsuccessful. We may find it necessary to enter into strategic partnerships, co-promotion or other licensing arrangements. To the extent we enter into such strategic partnerships, co-promotion or other licensing arrangements, our product revenues are likely to be lower than if we directly marketed and sold such drugs, and some or all of the revenues we receive will depend upon the efforts of third parties, which may not be successful and may not be within our control. If we are unable to enter into such strategic partnerships, co-promotion or other licensing arrangements on acceptable terms or at all, we may not be able to successfully commercialize our existing and future drug candidates. If we are not successful in commercializing any drug candidates, for which we obtain regulatory approval, either on our own or through collaborations with one or more third parties, our future product revenue will suffer, and we may never achieve profitability or become unable to continue the operation of our business.

***If our drug candidates for which we obtain regulatory approval do not achieve broad acceptance from physicians, patients and third-party payors, we may be unable to generate significant revenues, if any.***

Even if we obtain regulatory approval for our drug candidates, our approved drugs may not gain market acceptance among physicians and patients. We believe that effectively marketing our drug candidates, if any of them are approved, will require substantial efforts, both prior to commercial launch and after approval. Physicians may elect not to prescribe our drugs, and patients may elect not to request or take them, for a variety of reasons, including:

- limitations or warnings contained in a drug's FDA-approved labeling;
- changes in the standard of care or the availability of alternative drugs for the targeted indications for any of our drug candidates;
- limitations in the approved indications for our drug candidates;
- the approval, availability, market acceptance and reimbursement for the companion diagnostic, where applicable;
- demonstrated clinical safety and efficacy compared to other drugs;
- significant adverse side effects;
- effectiveness of education, sales, marketing and distribution support;
- timing of market introduction and perceived effectiveness of competitive drugs;
- cost-effectiveness;
- adverse publicity about our drug candidates or favorable publicity about competitive drugs;
- convenience and ease of administration of our drug candidates; and
- willingness of third-party payors to reimburse for the cost of our drug candidates.

If our future drugs fail to achieve market acceptance, we will not be able to generate significant revenues and may never achieve profitability.

***Even if any of our drug candidates receive FDA approval, the terms of the approval may limit such drug's commercial potential. Additionally, even after receipt of FDA approval, such drug would be subject to substantial, ongoing regulatory requirements.***

The FDA has complete discretion over the approval of our drug candidates. If the FDA grants approval, the scope of the approval may limit our ability to commercialize such drug, and in turn, limit our ability to generate substantial product revenue. For example, the FDA may grant approval contingent on the performance of costly post-approval clinical trials or subject to warnings or contraindications. Additionally, even after granting approval, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for such drug will be subject to extensive and ongoing regulatory requirements. In addition, manufacturers of our drug candidates are required to comply with cGMP regulations, which include requirements related to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Further, regulatory authorities must inspect and approve these manufacturing facilities before they can be used to manufacture our drug candidates, and these facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations. If we or a third party discover previously unknown problems with a drug, such as adverse events of unanticipated severity or frequency, or problems with the facility where the drug is manufactured, a regulatory authority may impose restrictions on that product, the manufacturer or us, including requiring withdrawal of the drug from the market or suspension of manufacturing. If we, our drug candidates or the manufacturing facilities for our drug candidates fail to comply with regulatory requirements of the FDA and/or other non-U.S. regulatory authorities, we could be subject to administrative or judicially imposed sanctions, including the following:

- warning letters;
- civil or criminal penalties and fines;
- injunctions;
- consent decrees;
- suspension or withdrawal of regulatory approval;
- suspension of any ongoing clinical studies;
- voluntary or mandatory product recalls and publicity requirements;
- refusal to accept or approve applications for marketing approval of new drugs;
- restrictions on operations, including costly new manufacturing requirements; or
- seizure or detention of drugs or import bans.

The regulatory requirements and policies may change, and additional government regulations may be enacted with which we may also be required to comply. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or in other countries. If we are not able to maintain regulatory compliance, we may not be permitted to market our future products and our business may suffer.

***Reimbursement decisions by third-party payors may have an adverse effect on pricing and market acceptance of any of our drug candidates. If there is not sufficient reimbursement for our future drugs, it is less likely that such drugs will be widely used.***

Market acceptance and sales of any of our drug candidates for which we obtain regulatory approval will depend on reimbursement policies and may be affected by future health care reform measures in both the United States and foreign jurisdictions. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will cover and establish payment levels. In addition, government authorities and these third-party payors are increasingly attempting to contain health care costs by demanding price discounts or rebates and limiting both the types and variety of drugs that they will cover and the amounts that they will pay for these drugs. In addition, we might need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of any future drugs to such payors' satisfaction. Such studies might require us to commit a significant amount of management time and financial and other resources.

Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on payments allowed for lower-cost products that are already reimbursed, may be incorporated into existing payments for other products or services and may reflect budgetary constraints and/or imperfections in Medicare or Medicaid data used to calculate these rates. Net prices for drugs may be reduced by mandatory discounts or rebates required by government health care programs. Such legislation, or similar regulatory changes or relaxation of laws that restrict imports of drugs from other countries, could reduce the net price we receive for any future marketed drugs. As a result, our future drugs might not ultimately be considered cost-effective.

We cannot be certain that reimbursement will be available for any drug candidates that we develop. Also, we cannot be certain that reimbursement policies will not reduce the demand for, or the price paid for, any future drugs. If reimbursement is not available or is available on a limited basis, we may not be able to successfully commercialize any drug candidates that we develop.

***Other factors could affect the demand for and sales and profitability of any drug candidates that we may commercialize in the future.***

In general, other factors that could affect the demand for and sales and profitability of our future drugs include, but are not limited to:

- the timing of regulatory approval, if any, of competitive drugs;
- our or any other of our partners' pricing decisions, as applicable, including a decision to increase or decrease the price of a drug, and the pricing decisions of our competitors;
- government and third-party payor reimbursement and coverage decisions that affect the utilization of our future drugs and competing drugs;
- negative safety or efficacy data from new clinical studies conducted either in the U.S. or internationally by any party, which could cause the sales of our future drugs to decrease or a future drug to be recalled;
- the degree of patent protection afforded our future drugs by patents granted to or licensed by us and by the outcome of litigation involving our or any of our licensor's patents;
- the outcome of litigation involving patents of other companies concerning our future drugs or processes related to production and formulation of those drugs or uses of those drugs;
- the increasing use and development of alternate therapies;
- the rate of market penetration by competing drugs; and
- the termination of, or change in, existing arrangements with our partners.

Any of these factors could have a material adverse effect on the sales of any drug candidates that we may commercialize in the future.

***Failure to obtain regulatory approvals in foreign jurisdictions will prevent us from marketing our products internationally.***

We may seek approval of our drug candidates outside the United States and may market future products in international markets. In order to market our future products in the European Economic Area, or EEA, and many other foreign jurisdictions, we must obtain separate regulatory approvals. Specifically, in the EEA, medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA.

Before granting the MA, the European Medicines Agency or the competent authorities of the member states of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

The approval procedures vary among countries and can involve additional clinical testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Clinical studies conducted in one country may not be accepted by regulatory authorities in other countries. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one or more foreign regulatory authorities does not ensure approval by regulatory authorities in other foreign countries or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. We may not be able to file for regulatory approvals, and even if we file we may not receive necessary approvals to commercialize our products in any market.

***If we obtain approval to commercialize any approved products outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.***

If our drug candidates are approved for commercialization outside of the United States, we expect that we will be subject to additional risks related to international operations and entering into international business relationships, including:

- different regulatory requirements for drug approvals;
- reduced protection for intellectual property rights, including trade secret and patent rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;

- workforce uncertainty in countries where employment regulations are different than, and labor unrest is more common than, in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters, including earthquakes, hurricanes, floods and fires; and
- difficulty in importing and exporting clinical trial materials and study samples.

**Risks Related to Reliance on Third Parties**

***We rely on third parties to plan, conduct and monitor our clinical tests, and their failure to perform as required would interfere with our product development.***

We rely on third parties to conduct a significant portion of our clinical development activities. These activities include clinical patient recruitment and observation, clinical trial monitoring, clinical data management and analysis, safety monitoring and project management. We conduct project management and medical and safety monitoring in-house for some of our programs and rely on third parties for the remainder of our clinical development activities. If any of these third parties is unable to perform in a quality and timely manner, and at a feasible cost, our clinical studies will face delays. Further, if any of these third parties fails to perform as we expect or if their work fails to meet regulatory standards, our testing could be delayed, cancelled or rendered ineffective.

***We rely on contract manufacturers over whom we have limited control. Should the cost, delivery and quality of clinical and commercial-grade materials manufactured by us in our Fall River facility or supplied by contract manufacturers vary to our disadvantage, our business operations could suffer significant harm.***

We have limited experience in commercial manufacturing. We plan to rely on CMOs to manufacture drug substance and drug product for our future late-stage clinical studies and for future commercial supplies. Our ability to conduct late-stage clinical trials, manufacture and commercialize our drug candidates, if regulatory approval is obtained, depends on the ability of such third parties to manufacture our drug candidates on a large scale at a competitive cost and in accordance with cGMP and foreign regulatory requirements, if applicable. We also rely on CMOs for filling, packaging, storage and shipping of drug product. In order for us to establish our own commercial manufacturing facility, we would require substantial additional funds and would need to hire and retain significant additional personnel and comply with extensive cGMP regulations applicable to such a facility. The commercial manufacturing facility would also need to be licensed for the production of our drug candidates by the FDA.

For our most advanced programs, we are working with CMOs under established manufacturing arrangements that comply with the FDA's requirements and other regulatory standards, although there is no assurance that the manufacturing will be successful. Prior to approval of any drug candidate, the FDA must review and approve validation studies for drug product. The manufacturing processes for our drug candidates and immunotherapeutic delivery systems utilize known technologies. We believe that the products we currently have under development can be scaled up to permit manufacture in commercial quantities. However, there can be no assurance that we will not encounter difficulties in scaling up the manufacturing processes. Significant scale-up of manufacturing may result in unanticipated technical challenges and may require additional validation studies that the FDA must review and approve. CMOs may encounter difficulties in scaling up production, including problems involving raw material suppliers, production yields, technical difficulties, scaled-up product characteristics, quality control and assurance, shortage of qualified personnel, capacity constraints, changing priorities within the CMOs, compliance with FDA and foreign regulations, environmental compliance, production costs and development of advanced manufacturing techniques and process controls. Any of these difficulties, if they occur and are not overcome to the satisfaction of the FDA or other regulatory agency, could lead to significant delays and possibly the termination of the development program for such drug candidate. These risks become more acute as we scale up for commercial quantities, where a reliable source of drug product becomes critical to commercial success. The commercial viability of any of our drug candidates, if approved, will depend on the ability of our contract manufacturers to produce drug product on a large scale. Failure to achieve this level of supply can jeopardize and prevent the successful commercialization of the drug.

We operate our own cGMP manufacturing facility in Fall River, Massachusetts, to produce drug substance for our current and planned early-stage clinical trials. Our Fall River manufacturing facility has 250L and 1000L bioreactor capacity and is able to manufacture in compliance with FDA regulations, allowing us to distribute potential products to clinical sites in the U.S. for early-stage clinical trials. We currently manufacture CDX-1140, CDX-301 and CDX-1401 drug substance and CDX-014 mAb intermediate in our Fall River facility for our current and planned Phase 1 and Phase 2 clinical trials. CDX-014, an ADC, is then manufactured by Lonza (Visp). We expect that our existing clinical supplies of CDX-3379 and varlilumab will be sufficient to carry out our current planned clinical development. Additional manufacturing options are under review and may involve utilization of the Fall River facility

and/or a CMO. All products are then filled and packaged at contract manufacturers. Any manufacturing failures or compliance issues at contract manufacturers could cause delays in our Phase 1 and Phase 2 clinical studies for these drug candidates.

Our leading drug candidates require specialized manufacturing capabilities and processes. We may face difficulty in securing commitments from U.S. and foreign contract manufacturers as these manufacturers could be unwilling or unable to accommodate our needs. Relying on foreign manufacturers involves peculiar and increased risks, including the risk relating to the difficulty foreign manufacturers may face in complying with cGMP requirements as a result of language barriers, lack of familiarity with cGMP or the FDA regulatory process or other causes, economic or political instability in or affecting the home countries of our foreign manufacturers, shipping delays, potential changes in foreign regulatory laws governing the sales of our product supplies, fluctuations in foreign currency exchange rates and the imposition or application of trade restrictions.

There can be no assurances that contract manufacturers will be able to meet our timetable and requirements. Further, contract manufacturers must operate in compliance with cGMP and failure to do so could result in, among other things, the disruption of product supplies. As noted above, non-U.S. contract manufacturers may face special challenges in complying with cGMP requirements, and although we are not currently dependent on non-U.S. collaborators or contract manufacturers, we may choose or be required to rely on non-U.S. sources in the future as we seek to develop stable supplies of increasing quantities of materials for ongoing clinical trials of larger scale. Our dependence upon third parties for the manufacture of our products may adversely affect our profit margins and our ability to develop, manufacture, sell and deliver products on a timely and competitive basis.

***We currently rely on sole suppliers for key components of our drug candidates. Any production problems with our suppliers or other disruptions in the supply of such components could adversely affect us.***

We currently rely on sole suppliers for key components of our drug candidates, including Hiltonol® for CDX-1401. While we work with the suppliers of these key components to ensure continuity of supply, no assurance can be given that these efforts will be successful. In addition, due to regulatory requirements relating to the qualification of suppliers, we may not be able to establish additional or replacement sources on a timely basis or without excessive cost. If our suppliers were to terminate our arrangements or fail to meet our supply needs, we might be forced to delay our development programs, or we could face disruptions in the distribution and sale of any drugs for which we obtain regulatory approval.

***Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them.***

Because we rely on third parties to develop our drug candidates, we must share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically restrict the ability of our collaborators, advisors, employees and consultants to publish data potentially relating to our trade secrets. Our academic collaborators typically have rights to publish data, provided that we are notified in advance and may delay publication for a specified time in order to secure our intellectual property rights arising from the collaboration. In other cases, publication rights are controlled exclusively by us, although in some cases we may share these rights with other parties. We also conduct joint research and development programs which may require us to share trade secrets under the terms of research and development partnership or similar agreements. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of these agreements, independent development or publication of information including our trade secrets in cases where we do not have proprietary or otherwise protected rights at the time of publication. A competitor’s discovery of our trade secrets would impair our competitive position.

**Risks Related to Business Operations**

***We recently implemented a plan to reduce our workforce and reprioritize our research and development pipeline. We may experience difficulties, delays or unexpected costs and not achieve anticipated benefits and savings from our restructuring plans.***

Following our recent announcement that our Phase 2b METRIC Study of glembatumumab vedotin failed to meet its primary endpoint, our decision to discontinue the glembatumumab vedotin program across all indications and our ongoing reprioritizing of its research and development pipeline, we implemented a reduction in force and terminated 41 employees in order to better align our resources with our operational needs going forward. These reductions in force will result in the loss of numerous long-term employees, the loss of institutional knowledge and expertise, and the reallocation of certain job responsibilities, all of which could negatively affect

operational efficiencies and increase our operating expenses such that we may not fully realize anticipated savings from the restructuring and could negatively affect our ability to advance our existing drug candidates through preclinical and clinical trials.

***We depend greatly on the intellectual capabilities and experience of our key executives, commercial personnel and scientists, and the loss of any of them could affect our ability to develop our products.***

The loss of any of our executive officers could harm us. We entered into employment agreements with each of our executive officers, although an employment agreement as a practical matter does not guarantee retention of an employee. We also depend on our scientific and clinical collaborators and advisors, all of whom have outside commitments that may limit their availability to us. In addition, we believe that our future success will depend in large part upon our ability to attract and retain highly skilled scientific, managerial and marketing personnel, particularly as we expand our activities in clinical trials, the regulatory approval process and sales and manufacturing. We routinely enter into consulting agreements with our scientific and clinical collaborators and advisors, key opinion leaders and heads of academic departments in the ordinary course of our business. We also enter into contractual agreements with physicians and institutions who recruit patients into our clinical trials on our behalf in the ordinary course of our business. Notwithstanding these arrangements, we face significant competition for this type of personnel from other companies, research and academic institutions, government entities and other organizations. We cannot predict our success in hiring or retaining the personnel we require for continued growth.

***In the future if we engage in a strategic transaction or raise additional capital, we may expand our clinical development, regulatory and sales and marketing capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.***

In the long-term, assuming we raise additional capital or engage in a strategic transaction, we expect we may require significant additional investment in personnel, management systems and resources, particularly the build out of our commercial capabilities. To date we have hired a core commercial team to plan for potential commercial launches if any of our drug candidates are approved. Over the next several years, we may experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, regulatory affairs and sales and marketing. To manage this potential future growth, we may continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

***We may not operate efficiently or realize the anticipated benefits of our acquisition of Kolltan.***

The success of the Kolltan merger will depend on, among other things, the combined company's ability to operate efficiently and to achieve its business objectives, including the successful development of its drug candidates. Achieving the benefits of the acquisition will depend in part on the successful development of the preclinical and clinical programs acquired from Kolltan. Following the acquisition, we decided to modify the Fc portion of CDX-0158 because approximately two-thirds of the patients in the Phase 1 dose-escalation study of CDX-0158 in patients with advanced refractory gastrointestinal stromal tumors, or GIST, and other KIT positive tumors had infusion reactions. This second-generation version, called CDX-0159, also includes modifications to increase the half-life of the antibody, giving it an additional advantage over CDX-0158. We are developing CDX-0159 in-house with the intention of replacing CDX-0158 in clinical development. As a result in the third quarter of 2017, we recorded a non-cash partial impairment charge of $13.0 million related to this clinical program due to changes in projected development and regulatory timelines. The time periods to receive approvals from the FDA and other regulatory agencies are subject to uncertainty and therefore we will continue to evaluate the development progress for the anti-KIT program and monitor the remaining $27.0 million intangible asset for further impairment. If we experience further delays or do not successfully develop the clinical programs acquired from Kolltan, we may incur further impairment charges and may not realize the anticipated benefits of the Kolltan acquisition, which would have an adverse effect on our business prospects and results of operations.

***Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.***

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with applicable privacy laws, comply with manufacturing standards we have established, comply with federal and state health care fraud and abuse laws and regulations, report

financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Business Conduct and Ethics and launched a Health Care Compliance program, but it is not always possible to identify and deter employee misconduct. The precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant effect on our business and results of operations, including the imposition of significant fines or other sanctions.

***We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.***

From time to time we may consider strategic transactions, including acquisitions of companies, such as our acquisition of Kolltan in the fourth quarter of 2016, asset purchases and out-licensing or in-licensing of products, drug candidates or technologies. Additional potential transactions that we may consider include a variety of different business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations, acquisitions of assets and investments. Any such transaction may require us to incur non-recurring or other charges, may increase our near and long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. For example, these transactions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention in order to develop acquired products, drug candidates or technologies;
- incurrence of substantial debt or dilutive issuances of equity securities to pay for acquisitions;
- higher than expected acquisition and integration costs;
- write-downs of assets or goodwill or impairment charges;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to retain key employees of any acquired businesses.

Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete could have a material adverse effect on our business, results of operations, financial condition and prospects.

***We may not be able to successfully integrate our existing technology or to modify our technologies to create new immunotherapeutic drugs.***

If we are able to integrate our acquired assets, such as Kolltan's drug development programs and TAM technology, and licensed assets with our immunotherapy technologies, we believe these assets will give our immunotherapeutic drugs a competitive advantage. However, if we are unable to successfully integrate licensed assets, or other technologies which we have acquired or may acquire in the future, with our existing technologies and potential products currently under development, we may be unable to realize any benefit from our acquisition of these assets, or other technologies which we have acquired or may acquire in the future, and we may face the loss of our investment of financial resources and time in the integration process.

We believe that our immunotherapy technology portfolio may offer opportunities to develop immunotherapeutic drugs that treat a variety of cancers and inflammatory and infectious diseases by stimulating a patient's immune system against those diseases. If our immunotherapy technology portfolio cannot be used to create effective immunotherapeutic drugs against a variety of diseases, we may lose all or portions of our investment in development efforts for new drug candidates.

***Our internal computer systems, or those of our CROs, CMOs, or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our drug development programs.***

Despite the implementation of security measures, our internal computer systems and those of our CROs, CMOs, and other contractors and consultants are vulnerable to damage from cyberattacks, malicious intrusion, computer viruses, unauthorized access, loss of data privacy, natural disasters, terrorism, war and telecommunication, electrical failures or other significant disruption. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs and commercialization efforts. For example, the loss of clinical study data from completed or ongoing clinical studies for any of our drug candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development or commercialization of our drug candidates could be delayed.

***Our business requires us to use hazardous materials, which increases our exposure to dangerous and costly accidents.***

Our research and development activities involve the use of hazardous chemicals, biological materials and radioactive compounds. Although we believe that our safety procedures for handling and disposing of hazardous materials comply with the standards prescribed by applicable laws and regulations, we cannot completely eliminate the risk of accidental contamination or injury from these materials. In the event of an accident, an injured party will likely sue us for any resulting damages with potentially significant liability. The ongoing cost of complying with environmental laws and regulations is significant and may increase in the future.

***We face the risk of product liability claims, which could exceed our insurance coverage, and product recalls, each of which could deplete our cash resources.***

As a participant in the pharmaceutical, biotechnology and immunotherapeutic drug industries, we are exposed to the risk of product liability claims alleging that use of our drug candidates caused an injury or harm. These claims can arise at any point in the development, testing, manufacture, marketing or sale of our drug candidates and may be made directly by patients involved in clinical trials of our products, by consumers or health care providers or by individuals, organizations or companies selling our products. Product liability claims can be expensive to defend, even if the drug or drug candidate did not actually cause the alleged injury or harm.

Insurance covering product liability claims becomes increasingly expensive as a drug candidate moves through the development pipeline to commercialization. Under our license agreements, we are required to maintain clinical trial liability insurance coverage up to $15 million. However, there can be no assurance that such insurance coverage is or will continue to be adequate or available to us at a cost acceptable to us or at all. We may choose or find it necessary under our collaborative agreements to increase our insurance coverage in the future. We may not be able to secure greater or broader product liability insurance coverage on acceptable terms or at reasonable costs when needed. Any liability for damages resulting from a product liability claim could exceed the amount of our coverage, require us to pay a substantial monetary award from our own cash resources and have a material adverse effect on our business, financial condition and results of operations. Moreover, a product recall, if required, could generate substantial negative publicity about our products and business and inhibit or prevent development of our drug candidates and, if approval is obtained, commercialization of our future drugs.

**Risks Related to Intellectual Property**

***We license technology from other companies to develop products, and those companies could influence research and development or restrict our use of it. In addition, if we fail to comply with our obligations in our intellectual property licenses with third parties, we could lose license rights that are important to our business.***

Companies that license technologies to us that we use in our research and development programs may require us to achieve milestones or devote minimum amounts of resources to develop products using those technologies. They may also require us to make significant royalty and milestone payments, including a percentage of any sublicensing income, as well as payments to reimburse them for patent costs. The number and variety of our research and development programs require us to establish priorities and to allocate available resources among competing programs. From time to time we may choose to slow down or cease our efforts on particular products. If in doing so we fail to fully perform our obligations under a license, the licensor can terminate the license or permit our competitors to use the technology. Termination of these licenses or reduction or elimination of our licensed rights may result in our having to negotiate new or reinstated licenses with less favorable terms. Moreover, we may lose our right to market and sell any products based on the licensed technology. The occurrence of such events could materially harm our business.

***Our ability to successfully develop and, if regulatory approval is obtained, commercialize our drug candidates may be materially adversely affected if we are unable to obtain and maintain effective intellectual property rights for our drug candidates and technologies.***

Our success depends in part on our ability to obtain and maintain patent protection and other intellectual property protection for our drug candidates and proprietary technology. We have sought to protect our proprietary position by filing patent applications in the United States and abroad related to our drug candidates and technology that are important to our business. This process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from using our technologies or from developing competing drugs and technologies.

Biotechnology patents involve complex legal, scientific and factual questions and are highly uncertain. To date, there is no consistent policy regarding the breadth of claims allowed in biotechnology patents, particularly in regard to patents for technologies for human uses like those we use in our business. We cannot predict whether the patents we or our licensors seek will issue. If such patents are issued, a competitor may challenge them and limit their scope. Moreover, our patents may not afford effective protection against competitors with similar technology. A successful challenge to any one of our patents could result in a third party's ability to use the technology covered by the patent. We also face the risk that others will infringe, avoid or circumvent our patents. Technology that we license from others is subject to similar risks and this could harm our ability to use that technology. If we, or a company that licenses technology to us, were not the first creator of an invention that we use, our use of the underlying product or technology will face restrictions, including elimination. For example, in September 2014, two European patent oppositions were filed against the University of Southampton European patent, and at a hearing on November 23, 2016 the European Patent Office (EPO) revoked the European patent on the ground of lack of inventive step. We intend to appeal this decision and to defend the European patent vigorously in cooperation with the University of Southampton. This EPO decision does not affect the later filed Celldex patents and applications for varlilumab. We also have an issued U.S. patent which covers varlilumab as a composition of matter.

If we must defend against suits brought against us or prosecute suits against others involving intellectual property rights, we will incur substantial costs. In addition to any potential liability for significant monetary damages, a decision against us may require us to obtain licenses to patents or other intellectual property rights of others on potentially unfavorable terms. If those licenses from third parties are necessary but we cannot acquire them, we would attempt to design around the relevant technology, which would cause higher development costs and delays and may ultimately prove impracticable.

***We may need to license intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.***

A third party may hold intellectual property, including patent rights, that are important or necessary to the development of our drug candidates. It may be necessary for us to use the patented or proprietary technology of a third party to commercialize our own technology or drug candidates, in which case we would be required to obtain a license from such third party. A license to such intellectual property may not be available or may not be available on commercially reasonable terms, which could have a material adverse effect on our business and financial condition.

We are aware of a third-party European patent that relates to use of ErbB3 antibodies for treatment of hyperproliferative disorders, including cancer. A counterpart of this patent has also issued in Japan and Australia. As a result of an opposition proceeding, the European patent was revoked in its entirety. The owner of the European patent has appealed the decision in the opposition proceeding. We do not know if the appeal will succeed, or, if successful, whether the scope of claims, post-appeal, would be relevant to our activities. Should the appeal be successful and a license be necessary for our program that targets ErbB3, we cannot predict whether we would be able to obtain such a license or, if a license were available, whether it would be available on commercially reasonable terms. If the appeal results in such third party's patents having a valid claim relevant to our use of ErbB3 antibodies and a license under the patents is unavailable on commercially relevant terms, or at all, our ability to commercialize CDX-3379 in Europe may be impaired or delayed. We would vigorously defend ourselves, but we cannot predict whether the patents would be found valid, enforceable or infringed. We continue to monitor counterpart patent applications pending in other jurisdictions, including the United States. While we cannot predict whether claims will issue in these other jurisdictions or whether the scope of such claims would be relevant to our activities, these applications entail comparable risks to us in these other jurisdictions.

***We may be unable to protect the confidentiality of our trade secrets, thus harming our business and competitive position.***

We rely upon trade secrets, including unpatented know-how, technology and other proprietary information to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with our employees and our collaborators and consultants. We also have agreements with our employees that obligate them to assign their inventions to us. However, it is possible that technology relevant to our business will be independently developed by a person that is not a party to such an agreement. Furthermore, if the employees, consultants or collaborators that are parties to these agreements breach or violate the terms of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets through such breaches or violations. Further, our trade secrets could be disclosed, misappropriated or otherwise become known or be independently discovered by our competitors. In addition, intellectual property laws in foreign countries may not protect our intellectual property to the same extent as the laws of the United States. If our trade secrets are disclosed or misappropriated, it would harm our ability to protect our rights and have a material adverse effect on our business.

***We may become involved in lawsuits to protect or enforce our patents, which could be expensive, time-consuming and unsuccessful.***

Competitors may infringe our patents. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

***Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.***

Our success depends upon our ability and the ability of our collaborators to develop and manufacture and, if regulatory approval is obtained, market and sell our drug candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the proprietary rights or intellectual property of third parties. We may become party to, or be threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our drug candidates and technology. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. If we are found to infringe a third-party's intellectual property rights, we could be required to obtain a license from such third-party to continue developing our drug candidates and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease developing the infringing technology or product. In addition, we could be found liable for monetary damages. Claims that we have misappropriated the confidential information or trade secrets of third parties can have a similar negative impact on our business.

***Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.***

We employ individuals who were previously employed at universities or other diagnostic or biopharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

**Regulatory Risks**

***If our processes and systems are not compliant with regulatory requirements, we could be subject to delays in submitting BLAs, NDAs or restrictions on marketing of drugs after they have been approved.***

We currently are developing drug candidates for regulatory approval and are in the process of implementing regulated processes and systems required to obtain and maintain regulatory approval for our drug candidates. Certain of these processes and systems for conducting clinical trials and manufacturing material must be compliant with regulatory requirements before we can apply for

regulatory approval for our drug candidates. These processes and systems will be subject to continual review and periodic inspection by the FDA and other regulatory bodies. If we are unable to achieve compliance in a timely fashion or if compliance issues are identified at any point in the development and approval process, we may experience delays in filing for regulatory approval for our drug candidates or delays in obtaining regulatory approval after filing. In addition, any later discovery of previously unknown problems or safety issues with approved drugs or manufacturing processes, or failure to comply with regulatory requirements may result in restrictions on such drugs or manufacturing processes, withdrawal of drugs from the market, the imposition of civil or criminal penalties or a refusal by the FDA and/or other regulatory bodies to approve pending applications for marketing approval of new drugs or supplements to approved applications, any of which could have a material adverse effect on our business. In addition, we are a party to agreements that transfer responsibility for complying with specified regulatory requirements, such as filing and maintenance of marketing authorizations and safety reporting or compliance with manufacturing requirements, to our collaborators and third-party manufacturers. If our collaborators or third-party manufacturers do not fulfill these regulatory obligations, any drugs for which we or they obtain approval may be subject to later restrictions on manufacturing or sale or may even risk withdrawal, which could have a material adverse effect on our business.

***Even if we receive regulatory approval for a drug candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and subject us to penalties if we fail to comply with applicable regulatory requirements.***

Once regulatory approval has been granted, the approved product and its manufacturer are subject to continual review by the FDA and/or non-U.S. regulatory authorities. Any regulatory approval that we or our collaboration partners receive for our drug candidates may be subject to limitations on the indicated uses for which the product may be marketed or contain requirements for potentially costly post-marketing follow-up studies to monitor the safety and efficacy of the product. In addition, if the FDA and/or non-U.S. regulatory authorities approve any of our drug candidates, we will be subject to extensive and ongoing regulatory requirements by the FDA and other regulatory authorities with regard to the labeling, packaging, adverse event reporting, storage, advertising, promotion and recordkeeping for our products. In addition, manufacturers of our drug products are required to comply with cGMP regulations, which include requirements related to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Further, regulatory authorities must inspect and approve these manufacturing facilities before they can be used to manufacture our drug products, and these facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations. If we or a third party discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency or problems with the facility where the product is manufactured, a regulatory authority may impose restrictions on that product, the manufacturer or us, including requiring withdrawal of the product from the market or suspension of manufacturing. If we, our drug candidates or the manufacturing facilities for our drug candidates fail to comply with regulatory requirements of the FDA and/or other non-U.S. regulatory authorities, we could be subject to administrative or judicially imposed sanctions, including the following:

- warning letters;
- civil or criminal penalties and fines;
- injunctions;
- consent decrees;
- suspension or withdrawal of regulatory approval;
- suspension of any ongoing clinical studies;
- voluntary or mandatory product recalls and publicity requirements;
- refusal to accept or approve applications for marketing approval of new drugs;
- restrictions on operations, including costly new manufacturing requirements; or
- seizure or detention of drugs or import bans.

The regulatory requirements and policies may change and additional government regulations may be enacted with which we may also be required to comply. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or in other countries. If we are not able to maintain regulatory compliance, we may not be permitted to market our future products, and our business may suffer.

***We may be subject, directly or indirectly, to federal and state health care fraud and abuse laws, false claims laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.***

If we obtain FDA approval for any of our drug candidates and begin commercializing those products in the United States, our operations will be directly, or indirectly through our customers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act. These laws may affect, among other things,

our proposed sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal health care program, such as the Medicare and Medicaid programs;

- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, which impose certain requirements relating to the privacy, security and transmission of individually identifiable health information;

- the federal transparency requirements under the Patient Protection and Affordable Care Act of 2010 requires manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests; and

- state law and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including exclusion from payment by federal health care programs, civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

***Compliance with laws and regulations pertaining to the privacy and security of health information may be time consuming, difficult and costly, particularly in light of increased focus on privacy issues in countries around the world, including the U.S. and the EU.***

We are subject to various domestic and international privacy and security regulations. The confidentiality, collection, use and disclosure of personal data, including clinical trial patient-specific information, are subject to governmental regulation generally in the country that the personal data were collected or used. In the United States were are subject to various state and federal privacy and data security regulations, including but not limited to HIPAA and as amended in 2014 by the HITECH Act. HIPAA mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common health care transactions, as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. In the EU personal data includes any information that relates to an identified or identifiable natural person with health information carrying additional obligations, including obtaining the explicit consent from the individual for collection, use or disclosure of the information. In addition, we are subject to EU regulation with respect to protection of and cross-border transfers of such data out of the EU, and this regulation will become more stringent in May 2018 when the EU's General Data Protection Regulation (GDPR) comes into effect. Furthermore, the legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues. The United States and the EU and its member states continue to issue new privacy and data protection rules and regulations that relate to personal data and health information.

Compliance with these laws may be time consuming, difficult and costly. If we fail to comply with applicable laws, regulations or duties relating to the use, privacy or security of personal data we could be subject to the imposition of significant civil and criminal penalties, be forced to alter our business practices and suffer reputational harm.

***Changes in health care law and implementing regulations, including government restrictions on pricing and reimbursement, as well as health care policy and other health care payor cost-containment initiatives, may have a material adverse effect on us.***

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the health care system and efforts to control health care costs, including drug prices, that could have a significant negative impact on our business, including preventing, limiting or delay regulatory approval of our drug candidates and reducing the sales and profits derived from our products once they are approved.

For example, in the United States, the Patient Protection and Affordable Care Act of 2010 ("ACA") substantially changed the way health care is financed by both governmental and private insurers and significantly affects the pharmaceutical industry. Many provisions of ACA impact the biopharmaceutical industry, including that in order for a biopharmaceutical product to receive federal reimbursement under the Medicare Part B and Medicaid programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the drug pricing program under the Public Health Services Act, or PHS. Since its enactment, there have been judicial and Congressional challenges and amendments to certain aspects of ACA. There is continued uncertainty about the implementation of ACA, including the potential for further amendments to the ACA and legal challenges to or efforts to repeal the ACA.

We cannot be sure whether additional legislative changes will be enacted, or whether government regulations, guidance or interpretations will be changed, or what the impact of such changes would be on the marketing approvals, sales, pricing, or reimbursement of our drug candidates or products, if any, may be.

**Risks Related to Our Capital Stock**

***Our history of losses and uncertainty of future profitability make our common stock a highly speculative investment.***

We have had no commercial revenue to date from sales of our drug candidates. We had an accumulated deficit of $812.5 million as of December 31, 2017. We expect to spend substantial funds to continue the research and development testing of our drug candidates.

In anticipation of FDA approval of these products, we will need to make substantial investments to establish sales, marketing, quality control, regulatory compliance capabilities and commercial manufacturing alliances. These investments will increase if and when any of these drug candidates receive FDA approval. We cannot predict how quickly our lead drug candidates will progress through the regulatory approval process. As a result, we may continue to lose money for several years.

We cannot be certain that we will achieve or sustain profitability in the future. Failure to achieve profitability could diminish our ability to sustain operations, pay dividends on our common stock, obtain additional required funds and make required payments on our present or future indebtedness.

***Our share price has been and could remain volatile.***

The market price of our common stock has historically experienced and may continue to experience significant volatility. From January 2017 through April 2018, the market price of our common stock has fluctuated from a high of $4.02 per share in the first quarter of 2017, to a low of $0.65 per share in the second quarter of 2018. Our progress in developing and commercializing our products, the impact of government regulations on our products and industry, the potential sale of a large volume of our common stock by stockholders, our quarterly operating results, changes in general conditions in the economy or the financial markets and other developments affecting us or our competitors could cause the market price of our common stock to fluctuate substantially with significant market losses. If our stockholders sell a substantial number of shares of common stock, especially if those sales are made during a short period of time, those sales could adversely affect the market price of our common stock and could impair our ability to raise capital. In addition, in recent years, the stock market has experienced significant price and volume fluctuations. This volatility has affected the market prices of securities issued by many companies for reasons unrelated to their operating performance and may adversely affect the price of our common stock. Adverse changes to the price of our common stock could result in an impairment to the amount recorded to goodwill on our balance sheet. In addition, we could be subject to a securities class action litigation as a result of volatility in the price of our stock, which could result in substantial costs and diversion of management's attention and resources and could harm our stock price, business, prospects, results of operations and financial condition.

***If certain preclinical and clinical milestones are achieved, our stockholders may experience significant dilution as a result of milestone payments to former Kolltan stockholders.***

The merger agreement pursuant to which we acquired Kolltan provides that, in the event that certain specified preclinical and clinical development milestones related to Kolltan's development programs and/or Celldex's development programs and certain

commercial milestones related to Kolltan's drug candidates are achieved, we will be required to pay Kolltan's stockholders milestone payments of up to $172.5 million, which milestone payments may be made, at our sole election, in cash, in shares of our common stock or a combination of both, subject to the provisions of the merger agreement. The number of shares of our common stock issuable in connection with a milestone payment, if any, will be determined based on the average closing price per share of our common stock for the five trading day period ending three calendar days prior to the achievement of such milestone. If we elect to issue additional shares of our common stock, in lieu of paying cash, for such milestone payments, our stockholders may experience significant dilution.

***Our ability to use our net operating loss carryforwards will be subject to limitation and, under certain circumstances, may be eliminated.***

Utilization of our net operating loss and research and development credit carryforwards may be subject to substantial annual limitation due to ownership change limitations that have occurred previously or that could occur in the future provided by Section 382 of the Internal Revenue Code of 1986, or Section 382, as well as similar state provisions. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50 percentage points over a three-year period.

In October 2007, June 2009, December 2009 and December 2013, we experienced a change in ownership as defined by Section 382 of the Internal Revenue Code. Historically, we have raised capital through the issuance of capital stock on several occasions which, combined with shareholders' subsequent disposition of those shares, has resulted in three changes of control, as defined by Section 382. As a result of these ownership changes, utilization of our Federal net operating loss carryforwards is subject to an annual limitation. Any unused annual limitation may be carried over to later years, and the amount of the limitation may, under certain circumstances, be subject to adjustment if the fair value of our net assets is determined to be below or in excess of the tax basis of such assets at the time of the ownership change, and such unrealized loss or gain is recognized during the five-year period after the ownership change. Subsequent ownership changes, as defined in Section 382, could further limit the amount of net operating loss carryforwards and research and development credits that can be utilized annually to offset future taxable income.

We have not undertaken a study to assess whether an ownership change or multiple ownership changes has occurred for (i) acquired businesses prior to the acquisition, (ii) the Company on the state level, (iii) the Company since March 2015 or (iv) research and development credits. If, based on such a study, we were to determine that there has been an ownership change at any time since its formation, utilization of net operating loss or tax credit carryforwards would be subject to an annual limitation under Section 382.

Refer to Note 15, "Income Taxes," in the notes to the financial statements in our Annual Report on Form 10-K for the year ended December 31, 2017 for additional discussion on income taxes.

**Item 5. Other Information**

Following the failure of our Phase 2b METRIC study to meet its primary endpoint, we evaluated the program asset for potential impairment related to the discontinuation of our glembatumumab vedotin program across all indications. Following such evaluation, on May 7, 2018, we determined that we should fully impair glembatumumab vedotin program and record a non-cash impairment charge of $18.7 million for the three months ended March 31, 2018. In addition, we recognized a $0.8 million non-cash income tax benefit, a $13.6 million gain on the contingent consideration liability related to the failure of the METRIC study and updated discount rates and a $91.0 million goodwill impairment charge as the carrying value of our net assets exceeded the fair value by the same amount. See Notes 2, 4 and 6 to the consolidated financial statements included elsewhere in this quarterly report on Form 10-Q for further discussion.

**Item 6. Exhibits**

The exhibits filed as part of this quarterly report on Form 10-Q are listed in the exhibit index immediately preceding the exhibits and are incorporated by reference herein.

**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.

**CELLDEX THERAPEUTICS, INC.**

BY:

/s/ ANTHONY S. MARUCCI

Dated: May 10, 2018

Anthony S. Marucci
President and Chief Executive Officer
(Principal Executive Officer)

/s/ SAM MARTIN

Dated: May 10, 2018

Sam Martin
Senior Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

## 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. |
| *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 | XBRL Instance Document. |
| *101 | XBRL Taxonomy Extension Schema Document. |
| *101 | XBRL Taxonomy Extension Calculation Linkbase Document. |
| *101 | XBRL Taxonomy Extension Definition Linkbase Document. |
| *101 | XBRL Taxonomy Extension Label Linkbase Document. |
| *101 | XBRL Taxonomy Extension Presentation Linkbase Document. |

* Filed herewith.
** Furnished herewith.

**Exhibit 31.1**

CERTIFICATION

I, Anthony S. Marucci, certify that:

1. I have reviewed this report on Form 10-Q of Celldex Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 10, 2018

By /s/ ANTHONY S. MARUCCI
Name: Anthony S. Marucci
Title: President and Chief Executive Officer

**Exhibit 31.2**

CERTIFICATION

I, Sam Martin, certify that:

1. I have reviewed this report on Form 10-Q of Celldex Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 10, 2018

By: /s/ SAM MARTIN
Name: Sam Martin
Title: Senior Vice President and Chief Financial Officer

**Exhibit 32.1**

SECTION 1350 CERTIFICATIONS

Pursuant to 18 U.S.C. §1350 as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, the undersigned officers of Celldex Therapeutics, Inc. (the "Company") hereby certify that to their knowledge and in their respective capacities that the Company's quarterly report on Form 10-Q to which this certification is attached (the "Report"), fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

| | | |
|---|---|---|
| Date: May 10, 2018 | By: | /s/ ANTHONY S. MARUCCI |
| | Name: | Anthony S. Marucci |
| | Title: | President and Chief Executive Officer |
| Date: May 10, 2018 | By: | /s/ SAM MARTIN |
| | Name: | Sam Martin |
| | Title: | Senior Vice President and Chief Financial Officer |

This certification shall not be deemed "filed" for any purpose, nor shall it be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Exchange Act. A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to Celldex Therapeutics, Inc. and will be retained by Celldex Therapeutics, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.