ALDER BIOPHARMACEUTICALS INC
Form 10-Q
August 07, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 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 June 30, 2018

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to

Commission File Number: 001-36431

Alder BioPharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	90-0134860
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

11804 North Creek Parkway South

Bothell, WA 98011

(Address of principal executive offices including zip code)

Registrant's telephone number, including area code: (425) 205-2900

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.

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 August 2, 2018 the registrant had 68,236,391 shares of common stock, $0.0001 par value per share, outstanding.

Alder BioPharmaceuticals, Inc.

Quarterly Report on Form 10-Q

For the Quarter Ended June 30, 2018

INDEX

In this Quarterly Report on Form 10-Q, "we," "our," "us," "Alder," and "the Company" refer to Alder BioPharmaceuticals, Inc and, where appropriate, its consolidated subsidiaries. "Alder," "Alder BioPharmaceuticals" and the Alder logo are the property of Alder BioPharmaceuticals, Inc. This report contains references to our trademarks and trade names and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this report may appear without the ® or ™ symbols, but such references are not intended to indicate, in any way, that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

PART I. – FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements
Alder BioPharmaceuticals, Inc.

Condensed Consolidated Balance Sheets

(unaudited)

	June 30, 2018	December 31, 2017
	(in thousands, except share and per share data)	
Assets		
Current assets		
Cash and cash equivalents	$115,754	$76,896
Short-term investments	192,810	199,344
Restricted cash	5,000	—
Prepaid expenses and other assets	7,641	11,014
Total current assets	321,205	287,254
Long-term investments	217,578	—
Property and equipment, net	4,537	5,630
Restricted cash	5,000	10,000
Investment in unconsolidated entity	—	222
Other assets	30	30
Total assets	$548,350	$303,136
Liabilities, convertible preferred stock and stockholders' equity		
Current liabilities		
Accounts payable	$15,735	$7,471
Accrued liabilities	13,720	15,803
Deferred rent	82	92
Total current liabilities	29,537	23,366
Long-term deferred rent	495	495
2025 convertible senior notes, net	176,052	—
Derivative liability	1,505	—
Total liabilities	207,589	23,861
Commitments and contingencies		
Series A-1 convertible preferred stock; $0.0001 par value; 10,000,000 shares authorized; 742,195 shares and no shares issued and outstanding, respectively; liquidation preference of $100,000 and zero, respectively	101,095	—
Stockholders' equity		
	7	7

Common stock; $0.0001 par value; 200,000,000 shares authorized; 68,153,074 and 67,842,942 shares issued and outstanding, respectively		
Additional paid-in capital	1,063,943	946,869
Accumulated deficit	(822,929)	(667,509)
Accumulated other comprehensive loss	(1,355)	(92)
Total stockholders' equity	239,666	279,275
Total liabilities, convertible preferred stock and stockholders' equity	$548,350	$303,136

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

Alder BioPharmaceuticals, Inc.

Condensed Consolidated Statements of Operations

(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
	(in thousands, except share and per share data)			
Revenues				
Collaboration and license agreements	$—	$683	$—	$683
Operating expenses				
Cost of sales	—	683	—	683
Research and development	52,818	65,276	126,866	155,965
General and administrative	12,154	9,548	23,816	19,529
Total operating expenses	64,972	75,507	150,682	176,177
Loss from operations	(64,972)	(74,824)	(150,682)	(175,494)
Other income (expense)				
Interest income	2,533	438	4,176	923
Foreign currency gain (loss)	243	(113)	352	(107)
Interest expense	(4,688)	—	(7,539)	—
Change in fair value of derivative liability	(1,505)	—	(1,505)	—
Total other income (expense), net	(3,417)	325	(4,516)	816
Net loss before equity in net loss of unconsolidated entity	(68,389)	(74,499)	(155,198)	(174,678)
Equity in net loss of unconsolidated entity	—	(130)	(222)	(279)
Net loss	$(68,389)	$(74,629)	$(155,420)	$(174,957)
Deemed dividends on convertible preferred stock attributable to accretion of beneficial conversion feature	—	—	(29,460)	—
Dividends on convertible preferred stock	(2,302)	—	(3,385)	—
Net loss applicable to common stockholders	$(70,691)	$(74,629)	$(188,265)	$(174,957)
Net loss per share applicable to common stockholders - basic and diluted	$(1.04)	$(1.48)	$(2.77)	$(3.47)
Weighted average number of common shares used in net loss per share - basic and diluted	67,966,066	50,427,865	67,905,804	50,411,837

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

Alder BioPharmaceuticals, Inc.

Condensed Consolidated Statements of Comprehensive Loss

(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
	(in thousands)		(in thousands)	
Net loss	$(68,389)	$(74,629)	$(155,420)	$(174,957)
Other comprehensive loss:				
Unrealized loss on securities available-for-sale, net of tax	(386)	(73)	(1,263)	(20)
Total other comprehensive loss	(386)	(73)	(1,263)	(20)
Comprehensive loss	$(68,775)	$(74,702)	$(156,683)	$(174,977)

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

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Alder BioPharmaceuticals, Inc.

Condensed Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity

(unaudited)

	Series A-1 Convertible Preferred Stock		Common Stock					
	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
			(in thousands, except for share data)					
Balances at December 31, 2017	—	$—	67,842,942	$ 7	$946,869	$ (667,509)	$ (92)	$279,275
Net loss	—	—	—	—	—	(155,420)	—	(155,420)
Other comprehensive loss	—	—	—	—	—	—	(1,263)	(1,263)
Issuance of Series A-1 convertible preferred stock, net of issuance costs of $2.3 million	725,268	97,710	—	—	—	—	—	—
Beneficial conversion feature on Series A-1 convertible preferred stock	—	(29,460)	—	—	29,460	—	—	29,460
Deemed dividend on convertible preferred stock attributable to accretion of beneficial conversion feature	—	29,460	—	—	(29,460)	—	—	(29,460)
Paid-in-kind dividends on convertible preferred stock	16,927	3,385	—	—	(3,385)	—	—	(3,385)
	—	—	—	—	109,911	—	—	109,911

Equity component of 2025 convertible senior notes								
Equity component of deferred financing costs for 2025 convertible senior notes	—	—	—	—	(3,763)	—	—	(3,763)
Stock-based compensation	—	—	—	—	13,169	—	—	13,169
Exercise of stock options	—	—	233,562	—	426	—	—	426
Shares issued under employee stock purchase plan	—	—	76,570	—	716	—	—	716
Balances at June 30, 2018	742,195	$101,095	68,153,074	$ 7	$1,063,943	$(822,929)	$ (1,355)	$239,666

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

Alder BioPharmaceuticals, Inc.

Condensed Consolidated Statements of Cash Flows

(unaudited)

	Six Months Ended June 30,	
	2018	2017
	(in thousands)	
Operating activities		
Net loss	$(155,420)	$(174,957)
Adjustments to reconcile net loss to net cash used in operating activities		
Equity in net loss of unconsolidated entity	222	279
Depreciation and amortization	1,608	1,486
Stock-based compensation	13,169	10,901
Accretion of discount on convertible notes	4,544	—
Non-cash change in fair value of derivative liability	1,505	—
Other non-cash charges, net	(1,460)	300
Changes in operating assets and liabilities		
Prepaid expenses and other assets	3,373	27,159
Accounts payable	8,026	9,837
Accrued liabilities	(2,083)	(1,201)
Deferred rent	(10)	(58)
Net cash used in operating activities	(126,526)	(126,254)
Investing activities		
Purchases of investments	(487,031)	(28,334)
Proceeds from maturities of investments	193,000	166,973
Proceeds from sales of investments	83,184	—
Purchases of property and equipment	(277)	(1,526)
Net cash provided by (used in) investing activities	(211,124)	137,113
Financing activities		
Proceeds from issuance of 2025 convertible senior notes, net of offering costs	277,656	—
Proceeds from issuance of convertible preferred stock, net of offering costs	97,710	—
Proceeds from exercise of stock options	1,142	714
Net cash provided by financing activities	376,508	714
Effect of exchange rate changes on cash, cash equivalents and restricted cash	—	—
Net increase in cash, cash equivalents and restricted cash	38,858	11,573
Cash, cash equivalents and restricted cash		
Beginning of period	86,896	116,216
End of period	$125,754	$127,789
Supplemental disclosures:		
Purchases of property and equipment included in accounts payable and accrued liabilities	$246	$101
Dividends on convertible preferred stock paid in kind	$3,385	$—

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

Alder BioPharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements

1. Nature of Business

Alder BioPharmaceuticals, Inc. (the "Company") is a clinical-stage biopharmaceutical company that discovers, develops and seeks to commercialize therapeutic antibodies with the potential to meaningfully transform the treatment paradigm in migraine. The Company has developed a proprietary antibody platform designed to select and manufacture antibodies that have the potential to maximize efficacy as well as speed of onset and durability of therapeutic response. The Company was incorporated in Delaware on May 20, 2002 and is located in Bothell, Washington.

Financings

On January 12, 2018, the Company completed a private placement of convertible preferred stock of 725,268 shares with certain institutional and other accredited investors. The Company received $97.7 million in net proceeds, after deducting fees and offering expenses of $2.3 million.

On February 1, 2018, the Company completed an underwritten public offering of an aggregate principal amount of $250 million of 2.5% Convertible Senior Notes due 2025 (the "Convertible Notes"). In addition, on February 13, 2018, the Company issued an additional $37.5 million principal amount of Convertible Notes to cover over-allotments. The Company received $277.7 million in net proceeds, after deducting fees and offering expenses of $9.8 million.

2. Summary of Significant Accounting Policies
Principles of Consolidation

The accompanying unaudited condensed consolidated financial statements reflect the accounts of Alder BioPharmaceuticals, Inc. and its wholly-owned subsidiaries, Alder BioPharmaceuticals Pty. Ltd., AlderBio Holdings LLC, and Alder BioPharmaceuticals Limited. All inter-company balances and transactions have been eliminated in consolidation. The condensed consolidated balance sheet data as of December 31, 2017 were derived from audited financial statements. The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission ("SEC") and generally accepted accounting principles in the United States of America ("GAAP") for unaudited condensed consolidated financial information. Accordingly, they do not include all of the information and notes required by GAAP for complete financial statements. The accompanying unaudited condensed consolidated financial statements reflect all adjustments consisting of normal recurring adjustments which, in the opinion of management, are necessary for a fair statement of the Company's financial position and results of its operations, as of and for the periods presented. The Company manages its business as one operating segment; however, the Company operates in three geographic regions: United States, Australia, and Ireland. Substantially all of the Company's assets are located in the United States.

The Company has a relationship with a variable interest entity ("VIE"). The Company evaluates VIEs to determine whether the Company is the primary beneficiary by performing a qualitative and quantitative analysis of each VIE that includes a review of, among other factors, the VIE's capital structure, contractual terms, related party relationships, the

Company's fee arrangements and the design of the VIE. This analysis includes determining whether the Company (1) has the power to direct matters that most significantly impact the activities of the VIE, and (2) has the obligation to absorb losses or the right to receive benefits of the VIE that could potentially be significant to the VIE.

In circumstances where the Company is not the primary beneficiary, but the Company has the ability to exercise significant influence over the operating and financial policies of a company in which it has an investment, the Company utilizes the equity method of accounting for recording investment activity. In assessing whether the Company exercises significant influence, it considers the nature and magnitude of the investment, the voting and protective rights held, any participation in the governance of the other company, and other relevant factors such as the presence of a collaboration or other business relationship. Under the equity method of accounting, the Company records in its results of operations its share of income or loss of the other company. If the Company's share of losses exceeds the carrying value of its investment, it will suspend recognizing additional losses and will continue to do so unless the Company commits to providing additional funding. The Company monitors its investment to evaluate whether any decline in value has occurred that would be other-than-temporary, based on the implied value of recent company financings, public market prices of comparable companies, and general market conditions. The carrying value of the investment is included in the Company's condensed consolidated balance sheet as investment in unconsolidated entity.

These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and accompanying notes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2017.

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. The results of the Company's operations for the three and six months ended June 30, 2018 are not necessarily indicative of the results to be expected for the full year or for any other period.

Concentrations of Credit Risk

The Company is exposed to credit risk from its deposits of cash, cash equivalents, short-term and long-term investments and restricted cash in excess of amounts insured by the Federal Deposit Insurance Corporation and Securities Investor Protection Corporation.

Restricted Cash

The Company had restricted cash of $10.0 million as of June 30, 2018, of which $5.0 million is classified as a current asset, as it will be used to satisfy commitments within the next 12 months. The funds are placed in an escrow account pursuant to a contractual agreement with a third-party manufacturer and will be used for payments under that agreement in 2019.

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the condensed consolidated balance sheets to the total of cash, cash equivalents and restricted cash shown in the condensed consolidated statement of cash flows.

	June 30, 2018	December 31, 2017
	(in thousands)	
Cash and cash equivalents	$115,754	$ 76,896
Restricted cash	10,000	10,000
Total cash, cash equivalents, and restricted cash shown in the consolidated statements of cash flows	$125,754	$ 86,896

Convertible Senior Notes, net

In accordance with accounting guidance for debt with conversion and other options, the Company separately accounted for the liability and equity components of the Convertible Notes by allocating the proceeds between the liability component and the embedded conversion option (the "Equity Component") due to the Company's ability to settle the Convertible Notes in cash, common stock or a combination of cash and common stock, at its option. The carrying amount of the liability component was calculated by measuring the fair value of a similar liability that does not have an associated convertible feature. The allocation was performed in a manner that reflected the Company's non-convertible debt borrowing rate for similar debt. The Equity Component of the Convertible Notes was recognized as a debt discount and represents the difference between the proceeds from the issuance of the Convertible Notes and

the fair value of the liability of the Convertible Notes on their respective dates of issuance. The excess of the principal amount of the liability component over its carrying amount (the "Debt Discount") is amortized to interest expense using the effective interest method over seven years. The Equity Component is not remeasured as long as it continues to meet the conditions for equity classification. In connection with the issuance of the Convertible Notes, the Company also incurred certain offering costs directly attributable to the offering. Such costs are deferred and amortized over the term of the debt to interest expense using the effective interest method. A portion of the deferred financing costs incurred in connection with the Convertible Notes was deemed to relate to the Equity Component and was allocated to additional paid-in capital.

Convertible preferred stock

The Company recorded the convertible preferred stock at fair value on the date of issuance, net of issuance costs. The convertible preferred stock is recorded outside of stockholders' equity because, in the event of certain deemed liquidation events considered not solely within the Company's control, such as a merger, acquisition and sale of all or substantially all of the Company's assets, the convertible preferred stock will become redeemable at the option of the holders.

Revenue recognition

In May 2016, the Company licensed the exclusive worldwide rights to its product candidate clazakizumab to Vitaeris, Inc. ("Vitaeris"), a newly formed company based in Vancouver, British Columbia. In exchange for the rights to clazakizumab, the

Company received an equity interest in Vitaeris and is eligible to receive royalties and certain other payments including revenue from the sale of drug supply inventory. The Company did not record any revenue under this agreement in the three and six months ended June 30, 2018 and recorded $0.7 million in revenue in the three and six months ended June 30, 2017.

In the future, the Company may generate revenue from product sales and may enter into agreements with strategic partners for the development and commercialization of the Company's products under which revenues may consist of license fees, non-refundable upfront fees, milestones, funding of research and development activities, sales of drug supply, or other revenue. The Company could receive both fixed and variable consideration.

On January 1, 2018, the Company adopted ASC Topic 606 and related pronouncements regarding revenue recognition using the modified retrospective method. The adoption of this guidance did not have a material impact on the Company's condensed consolidated financial statements. In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under its agreements, the Company will perform the following steps: (i) assess whether collectability is probable; (ii) identify the promised goods or services in the contract; (iii) determine whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iv) measure the transaction price, including the constraint on variable consideration; (v) allocate the transaction price to the performance obligations based on estimated selling prices; and (vi) recognize revenue when (or as) the Company satisfies each performance obligation.

A performance obligation is a promise in a contract to transfer a distinct good or service to the customer and is the unit of accounting in ASC Topic 606. The Company's performance obligations may include license rights and development services. Significant management judgment will be required to determine the level of effort required under an arrangement and the period over which the Company expects to complete its performance obligations under the arrangement.

When the Company has substantive performance obligations under an arrangement accounted for as one unit of accounting, revenues will be recognized using a proportional performance-based approach. Under this approach, revenue recognition is based on costs incurred to date compared to total expected costs to be incurred over the performance period as this is considered to be representative of the delivery of service under the arrangement. Changes in estimates of total expected performance costs or service obligation time-period will be accounted for prospectively as a change in estimate. Revenues recognized at any point in time will be limited to the amount of noncontingent payments received or due.

The Company will allocate the total transaction price to each performance obligation based on the estimated relative standalone selling prices of the promised goods or service underlying each performance obligation. Estimated selling prices for license rights will be calculated using vendor-specific objective evidence, ("VSOE"), of selling price, if available, third-party evidence, ("TPE"), of selling price if VSOE is not available, or best estimate of selling price, ("BESP"), if neither VSOE nor TPE is available, and include the following key assumptions: the development timeline, revenue forecast, commercialization expenses, discount rate and probabilities of technical and regulatory success.

Licenses of intellectual property: If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company will recognize revenues from non-refundable, up-front fees allocated to the license when the license is transferred to the customer, and the customer can use and benefit from the license. For licenses that are bundled with other promises, the Company will utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company will evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and

related revenue recognition.

Milestone payments: At the inception of each arrangement that includes milestone payments, the Company will evaluate whether the milestones are considered probable of being achieved and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the value of the associated milestone (such as a regulatory submission by the Company) will be included in the transaction price. Milestone payments that are not within the control of the Company, such as approvals from regulators, will not be considered probable of being achieved until those approvals are received. When the Company's assessment of probability of achievement changes and variable consideration becomes probable, any additional estimated consideration will be allocated to each performance obligation based on the estimated relative standalone selling prices of the promised goods or service underlying each performance obligation and recorded in license, collaboration, and other revenues based upon when the customer obtains control of each element.

Royalties: For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company will recognize revenue at the later of (a) when the related sales occur, or (b) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Collaboration payments: The Company may also perform research and development activities on behalf of collaborative partners that are paid for by the collaborators. For research and development activities which are not determined to be separate units of accounting based on the criteria above, revenues for these research and development activities will be recognized using the single unit

of accounting method for that collaborative arrangement. For research and development activities which are determined to be separate units of accounting, arrangement consideration will be allocated and revenues will be recognized as services are delivered, assuming the general criteria for revenue recognition noted above have been met. The corresponding research and development costs incurred under these contracts will be included in research and development expense in the consolidated statements of operations. For sales of drug supply inventory at cost, the revenue will be recognized upon transfer of the inventory.

The Company expects to invoice its customers upon the completion of the effort, based on the terms of each agreement. Amounts earned, but not yet collected from the customers, if any, will be included in accounts receivable in the accompanying consolidated balance sheets. Deferred revenue will arise from payments received in advance of the culmination of the earnings process. Deferred revenue expected to be recognized within the next 12 months will be classified as a current liability. Deferred revenue will be recognized as revenue in future periods when the applicable revenue recognition criteria have been met.

Long-Term Incentive Plan

In January 2018, the Company established a long-term incentive plan ("LTIP") which provides eligible employees with the opportunity to receive performance-based compensation comprised of restricted stock units. The vesting of the restricted stock units is contingent upon the achievement of pre-determined regulatory milestones. The Company records compensation expense over the estimated service period for a milestone when the achievement of the milestone is considered probable, which is assessed at each reporting date. Once a milestone is considered probable, the Company records compensation expense based on the portion of the service period elapsed to date with respect to that milestone, with a cumulative catch-up, net of estimated forfeitures, and recognizes any remaining compensation expense, if any, over the remaining estimated service period. No compensation expense has been recorded to date under the LTIP as the conditions for recognizing expense have not yet been met. As of June 30, 2018, the estimated value to be delivered in restricted stock units to participants eligible for the LTIP was approximately $9.7 million. The total potential value to be delivered under the LTIP is expected to change in the future for several reasons, including the addition of more eligible employees to the LTIP.

2018 Inducement Award Plan

On June 11, 2018, the Company established the 2018 Inducement Award Plan ("Inducement Plan"). The Inducement Plan allows for the grant of options, restricted stock, restricted stock unit awards, and performance unit awards to new employees of the Company by granting an award to such new employee as an inducement to begin employment with the Company. The Company reserved 3,000,000 shares of its common stock for issuance under the Inducement Plan. As of June 30, 2018, there were 1,850,000 shares of common stock reserved for issuance.

Liquidity and Going Concern

The Company has an accumulated deficit as of June 30, 2018. To date, the Company has funded its operations primarily through sales of its capital stock and Convertible Notes and payments from its former collaboration partners, and will require substantial additional capital for research and product development. In January 2018, the Company completed a private placement of 725,268 shares of convertible preferred stock resulting in net proceeds of $97.7 million. In February 2018, the Company received $277.7 million in net proceeds from the underwritten public offering of the Convertible Notes.

The Company forecasts a significant increase in expenditures to support its planned Biologics License Application ("BLA") submission with the U.S. Food and Drug Administration, currently anticipated to occur in the first quarter of 2019, commercial readiness activities and anticipated commercial launch of eptinezumab. The Company estimates the

available cash, cash equivalents, short-term and long-term investments and restricted cash as of June 30, 2018 will be sufficient to meet the Company's projected operating requirements into 2020. These operating requirements consist principally of expenditures related to the planned BLA submission, establishment of the eptinezumab commercial drug supply chain, continued build-out of the Company's commercial organization (e.g., marketing, sales, medical affairs, payor access, information technology) and pre-launch market readiness. The Company has based its estimate on the timing for its projected expenditures on assumptions that may prove to be wrong, and it could utilize its available capital resources sooner than it currently expects. Furthermore, the Company's operating plans may change, and it may need additional funds to meet operational needs and capital requirements sooner than planned. The Company will need additional funding to execute the commercial launch of eptinezumab. The Company will also need to obtain substantial additional sources of funding to develop and commercialize ALD1910 and its other product candidates. The Company expects to finance future cash needs through equity financings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements, but there are no assurances that the Company will be able to raise sufficient amounts of funding in the future on acceptable terms, or at all.

The condensed consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates continuity of operations, the realization of assets and the satisfaction of liabilities and commitments in the normal course of business.

Recent Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board (FASB) issued ASU 2016-02, Leases. This ASU requires the recognition of lease assets and lease liabilities on the balance sheet and disclosure of key information about leasing arrangements. In July 2018, the FASB issued ASU 2018-10, Codification Improvements to Topic 842, Leases. ASU 2016-02 and ASU 2018-10 will become effective for annual periods beginning after December 15, 2018. The Company expects adopting this guidance will result in an increase in the assets and liabilities on its consolidated balance sheets and will have some impact on its consolidated statements of operations and statement of cash flows.

In June 2018, the FASB issued ASU 2018-07, Compensation-Stock Compensation (Topic 718) – Improvements to Nonemployee Share-Based Payment Accounting. The amendment substantially aligns accounting for share-based payments to employees and non-employees. This ASU will become effective for annual periods beginning after December 15, 2018, including interim periods within that period, and early adoption is permitted. The Company is currently evaluating the effect of this new guidance on its consolidated financial statements.

The Company has reviewed other recent accounting pronouncements and concluded that they are either not applicable to the business, or that no material effect is expected on the condensed consolidated financial statements as a result of future adoption.

3. Net Loss Per Share Applicable to Common Stockholders

Basic net loss per share applicable to common stockholders is calculated by dividing net loss applicable to common stockholders by the weighted average common shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by adjusting the weighted average common shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock method.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Net loss applicable to common stockholders (in thousands)	$(70,691)	$(74,629)	$(188,265)	$(174,957)
Denominator				
Weighted average common shares outstanding - basic and diluted	67,966,066	50,427,865	67,905,804	50,411,837
Net loss per share applicable to common stockholders - basic and diluted	$(1.04)	$(1.48)	$(2.77)	$(3.47)

The following weighted average numbers of securities were excluded from the calculation of diluted net loss per share for the three and six months ended June 30, 2018 and 2017 because including them would have had an anti-dilutive effect. Therefore, basic and diluted net loss per share were the same for all periods presented.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Common shares underlying 2025 convertible senior notes	14,197,531	—	11,643,135	—
Common shares underlying convertible preferred stock	7,254,541	—	6,812,845	—
Stock options and awards	10,122,191	6,795,748	9,409,538	6,381,733
Employee stock purchase plan	87,835	61,354	182,106	116,887
	31,662,098	6,857,102	28,047,624	6,498,620

4. Investments

Investments consisted of available-for-sale securities as follows:

	Amortized Cost	Gross unrealized gains	Gross unrealized losses	Fair Value
	(in thousands)			
Type of security as of June 30, 2018				
U.S. government agency obligations maturing in one year or less	$193,095	$ —	$ (285)	$192,810
U.S. government agency obligations maturing after one year through two years	218,646	—	(1,068)	217,578
Total available-for-sale securities	$411,741	$ —	$ (1,353)	$410,388
Type of security as of December 31, 2017				
U.S. government agency obligations maturing in one year or less	$199,434	$ —	$ (90)	$199,344
Total available-for-sale securities	$199,434	$ —	$ (90)	$199,344

Realized gains and losses are determined based on the specific identification method and are reported in other income in the condensed consolidated statement of operations. During the three and six months ended June 30, 2018, the Company recorded $0.3 million in realized losses related to available-for-sale securities included in the Company's condensed consolidated statement of operations. There were no realized gains or losses on sales of available-for-sale securities in the three and six months ended June 30, 2017.

5. Investment in Unconsolidated Entity and Derivative Liability

In May 2016, the Company licensed the exclusive worldwide rights to its product candidate clazakizumab to Vitaeris. In exchange for the rights to clazakizumab, the Company received an equity stake in Vitaeris and is eligible to receive royalties and certain other payments. Since clazakizumab was developed internally by the Company, all previous expenditures to develop the compound were recognized as expense in the period incurred and there was no carrying value on the Company's condensed consolidated balance sheet. In 2016, the Company recognized a gain on the license agreement of $1.1 million, which was determined as the initial fair value of the Company's equity stake in Vitaeris.

Vitaeris is a VIE for which the Company is not the primary beneficiary as the Company does not have the power to direct the activities that most significantly influence the economic performance of the entity. In addition to the Company's exchange of license rights for clazakizumab, Vitaeris was capitalized through cash investments by other parties. The investment in Vitaeris is accounted for under the equity method of accounting because the Company holds common stock of Vitaeris and has significant influence over the operating and financial policies of Vitaeris

through its ownership, license arrangement and representation on the board of directors. Therefore, the Company records its share of any loss or income generated by Vitaeris, which is recorded on a three-month lag, within the condensed consolidated statement of operations. The investment is reflected as an investment in unconsolidated entity on the Company's condensed consolidated balance sheet which represents the investment in Vitaeris, net of the Company's portion of any generated loss or income. The Company recorded $0.2 million in net loss with respect to Vitaeris for the six months ended June 30, 2018, which was the remaining balance of the carrying value of the Company's investment in Vitaeris. The Company has no implied or unfunded commitments related to Vitaeris and its maximum exposure to loss is limited to the current carrying value of the investment.

In November 2017, the Company and Vitaeris amended the license agreement for clazakizumab and Vitaeris and its shareholders, including the Company, entered into a strategic collaboration and purchase option agreement (the "option agreement") with a third party, CSL Limited ("CSL"), an Australian entity, to expedite the development of clazakizumab as a therapeutic option for solid organ transplant rejection. Pursuant to the option agreement, CSL will provide research funding to Vitaeris for the development of clazakizumab and CSL received an exclusive option to acquire Vitaeris, subject to certain terms and conditions. Upon the execution of the option agreement, Vitaeris received an upfront payment of $15 million and Vitaeris will also receive future development milestone payments. If CSL exercises its purchase option, it will be required to make to Vitaeris' shareholders, including the Company, an immediate one-time payment and thereafter certain sales-based milestone payments. The Company will continue to be eligible to receive royalties and certain other payments following an acquisition of Vitaeris by CSL. The purchase option created a written call on the Company's shares in Vitaeris which was determined to have a fair value of $1.5 million as of June

30, 2018 and is considered a derivative under GAAP (see Note 6). The Company recorded a derivative liability on its condensed consolidated balance sheets and as other expense on its condensed consolidated statement of operations. The Company will assess the fair value of the derivative at each reporting period.

6. Fair Value Disclosures

The Company holds financial instruments that are measured at fair value which is determined according to a fair value hierarchy that prioritizes the inputs and assumptions used, and the valuation techniques used to measure fair value. The three levels of the fair value hierarchy are described as follows:

Level 1	Inputs are unadjusted quoted prices in active markets for identical assets or liabilities.
Level 2	Inputs are quoted prices for similar assets and liabilities in active markets or quoted prices for identical or similar instruments in markets that are not active and model-derived valuations in which all significant inputs and significant value drivers are observable in active markets.
Level 3	Inputs are unobservable inputs based on the Company's own assumptions and valuation techniques used to measure assets and liabilities at fair value. The inputs require significant management judgment or estimation.

The Company's assessment of the significance of a particular input to the fair value measurement requires judgment and may affect the valuation of fair value assets and liabilities and their placement within the fair value hierarchy levels.

The Company established the fair value of its assets and liabilities using the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date and established a fair value hierarchy based on the inputs used to measure fair value.

The following table presents the Company's financial instruments by level within the fair value hierarchy:

	Fair Value Measurement Using			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
As of June 30, 2018				
Assets				
Cash equivalents				
Money market funds	$89,636	$—	$ —	$89,636
Short-term investments				
U.S. government agency obligations	—	192,810	—	192,810
Long-term investments				
U.S. government agency obligations	—	217,578	—	217,578
Restricted cash				
Money market funds	10,000	—	—	10,000
	$99,636	$410,388	$ —	$510,024
Liabilities				
2025 convertible senior notes	—	299,180	—	299,180
	$—	$299,180	$ —	$299,180
As of December 31, 2017				
Cash equivalents				
Money market funds	$71,379	$—	$ —	$71,379
Short-term investments				
U.S. government agency obligations	—	199,344	—	199,344
Restricted cash				
Money market funds	10,000	—	—	10,000
	$81,379	$199,344	$ —	$280,723

The Company's negotiable certificates of deposit and U.S. government agency obligations are valued using fair value measurements that are considered to be Level 2. The investment custodian provides the Company with valuations of its securities portfolio. The primary source for the security valuation is Interactive Data Corporation ("IDC"), which evaluates securities based on market data. IDC utilizes evaluated pricing models that vary by asset class and include available trade, bid, and other market information. Generally, the methodology includes broker quotes, proprietary models, vast descriptive terms and conditions databases, as well as extensive quality control programs. The custodian utilizes proprietary valuation matrices for valuing all negotiable certificates of deposit.

Accounts payable and accrued liabilities are carried at cost, which approximates fair value due to the short-term nature of these financial instruments.

Fair Value of Convertible Notes

The fair value of the Convertible Notes is determined based upon data from readily available pricing sources which utilize market observable inputs and other characteristics for similar types of instruments and is included in Level 2 of the fair value hierarchy. See Note 8 for information about the determination of the carrying value of the Convertible Notes at June 30, 2018.

Fair Value of Derivative Liability

The fair value of the derivative liability related to the purchase option under which CSL could acquire the Company’s interest in Vitaeris (see Note 5) was $1.5 million as of June 30, 2018. The fair value of the derivative liability was not significant as of December 31, 2017. In accordance with ASC 815, Derivatives and Hedging, the fair value of a derivative is required to be recorded on the balance sheet with any changes in fair value recorded in earnings. The determination of the fair value requires judgment based on significant inputs not observable in the market which represents a Level 3 measurement within the fair value hierarchy. If factors change and different assumptions are used, the fair value of the derivative liability and related gains or losses could be materially different in the future.

7. Accrued Liabilities

Accrued liabilities consisted of the following for the dates indicated:

	June 30, 2018	December 31, 2017
	(in thousands)	
Compensation and benefits	$6,438	$7,933
Contracted research and development	3,420	6,846
Professional services and other	867	1,024
Interest on 2025 convertible senior notes	2,995	—
	$13,720	$15,803

8. 2025 Convertible Senior Notes, net

On February 1, 2018, the Company issued $250.0 million aggregate principal amount of the Convertible Notes in a registered underwritten public offering. In addition, on February 13, 2018, the Company issued an additional $37.5 million principal amount of Convertible Notes pursuant to the exercise of an over-allotment option granted to the underwriters in the offering.

The Convertible Notes are senior unsecured obligations of the Company and bear interest at a rate of 2.5% per annum, payable semi-annually in arrears on February 1 and August 1 of each year, commencing on August 1, 2018. Upon conversion, the Convertible Notes will be convertible into cash, shares of the Company’s common stock or a combination of cash and shares of the Company’s common stock, at the Company’s election. The Convertible Notes will be subject to redemption at the Company’s option, on or after February 1, 2022, in whole or in part, if the conditions described below are satisfied. The Convertible Notes will mature on February 1, 2025, unless earlier converted, redeemed or repurchased in accordance with their terms. Subject to satisfaction of certain conditions and during the periods described below, the Convertible Notes may be converted at an initial conversion rate of 49.3827 shares of common stock per $1,000 principal amount of the Convertible Notes (equivalent to an initial conversion price of approximately $20.25 per share of common stock). The conversion rate will be subject to adjustment in some events but will not be adjusted for any accrued and unpaid interest. In addition, if certain corporate events occur prior to the maturity date, the Company will increase the conversion rate for a holder of Convertible Notes who elects to convert its Convertible Notes in connection with such a corporate event in certain circumstances.

Holders of the Convertible Notes may convert all or any portion of their notes, in multiples of $1,000 principal amount, at their option at any time prior to the close of business on the business day immediately preceding November 1, 2024 only under the following circumstances:

1. during any calendar quarter commencing after the calendar quarter ending on March 31, 2018 (and only during such calendar quarter), if the last reported sale price of the Company's common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on the last trading day of the

immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day;

2. during the five business day period after any five consecutive trading day period (the “measurement period”) in which the "trading price" per $1,000 principal amount of the Convertible Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of the Company’s common stock and the conversion rate on each such trading day;
3. if the Company calls any or all of the Convertible Notes for redemption, at any time prior to the close of business on the scheduled trading day immediately preceding the redemption date; or
4. upon the occurrence of specified corporate events.

On or after November 1, 2024 and prior to the close of business on the business day immediately preceding February 1, 2025, holders may convert their Convertible Notes at any time.

Prior to February 1, 2022, the Company may not redeem the Convertible Notes. On or after February 1, 2022, the Company may redeem any or all of the Convertible Notes at a redemption price equal to 100% of the principal amount of the Convertible Notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date, if the last reported sale price of the Common Stock for at least 20 trading days (whether or not consecutive) during the period of 30 consecutive trading days ending on the trading day immediately prior to the date of the redemption notice exceeds 130% of the applicable conversion price for the Convertible Notes on each applicable trading day. If a “make-whole fundamental change” (as defined in the indenture) occurs prior to February 1, 2025, the Company will, in certain circumstances, increase the conversion rate for a holder who elects to convert its Convertible Notes in connection with the make-whole fundamental change.

The Convertible Notes do not contain any financial or operating covenants or any restrictions on the payment of dividends, the issuance of other indebtedness or the issuance or repurchase of securities by the Company. The Convertible Notes indenture contains customary events of default, including that upon certain events of default, 100% of the principal and accrued and unpaid interest on the Convertible Notes will automatically become due and payable.

In accordance with accounting guidance for debt with conversion and other options, the Company separately accounted for the embedded conversion feature of the Convertible Notes by allocating the proceeds between the liability component and the Equity Component, due to the Company's ability to settle the Convertible Notes in cash, common stock or a combination of cash and common stock, at its option. The initial amount of the liability component of $177.6 million was calculated by measuring the fair value of a similar liability that does not have an associated convertible feature and the residual between the proceeds from the issuance of $287.5 million and the fair value of the liability of $177.6 million is allocated to the Equity Component, which was recorded at $109.9 million and recognized as a debt discount. In addition, the Company incurred approximately $9.8 million of debt issuance costs, which primarily consisted of underwriting, legal and other professional fees. The issuance costs were allocated to the liability component and Equity Component proportionally based on the allocation of total proceeds. A total of $3.7 million was allocated to the Equity Component and recorded as a reduction to additional paid-in capital and $6.1 million was allocated to the liability component and is recorded as a reduction of the Convertible Notes in the Company’s condensed consolidated balance sheet.

The debt discount and the issuance costs will be amortized to interest expense using the effective interest method over seven years, the expected life of the Convertible Notes as discussed below. The Equity Component is not remeasured as long as it continues to meet the conditions for equity classification. During the three and six months ended June 30, 2018, the Company recorded $2.9 million and $4.5 million of interest expense related to the amortization of the debt discount and issuance costs in 2018, respectively. The unamortized balance of the liability was $176.1 million as of June 30, 2018.

While the Convertible Notes are classified on the Company’s condensed consolidated balance sheet at June 30, 2018 as long-term, the resulting balance sheet classification of this liability will be monitored at each quarterly reporting date and will be analyzed dependent upon whether the Convertible Notes are convertible or subject to an event triggering potential redemption during the prescribed measurement periods. In the event that the holders of the Convertible Notes have the election to convert the Convertible Notes or the Convertible Notes become redeemable at any time during the prescribed measurement period, the Convertible Notes would then be considered a current obligation and classified as such.

While for GAAP purposes, the Convertible Notes are allocated between the liability component and the Equity Component, for U.S. tax purposes there is no allocation, and a deferred tax liability is recognized related to such difference. Because the Company has a full valuation allowance recorded against net deferred tax assets, there is no net impact on the Company’s condensed consolidated balance sheets or condensed consolidated statements of operations as a result of establishing this deferred tax liability.

The outstanding balances of the Convertible Notes as of June 30, 2018 consisted of the following:

	2025 Convertible Senior Notes

	(in thousands)
Liability component:	
Principal	$ 287,500
Less: unamortized debt discount and issuance costs	(111,448)
Net carrying amount	$ 176,052
Net carrying amount of Equity Component	$ 106,148

The Company determined the expected life of the Convertible Notes was equal to its seven-year term and the effective interest rate on the liability component was 10.6%. As of June 30, 2018, the “if-converted value” did not exceed the remaining principal amount of the Convertible Notes. The fair value of the Convertible Notes is based on data from readily available pricing sources which utilize market observable inputs and other characteristics for similar types of instruments, and, therefore, these Convertible Notes are classified within Level 2 in the fair value hierarchy. The fair value of the Convertible Notes, which differs from their carrying value, is influenced by interest rates, the Company’s stock price and stock price volatility. The estimated fair value of the Convertible Notes as of June 30, 2018 was approximately $299.2 million.

The following table sets forth total interest expense recognized related to the Convertible Notes during the three and six months ended June 30, 2018 and 2017:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
	(in thousands)		(in thousands)	
Contractual interest expense	$ 1,833	$ —	$ 2,995	$ —
Amortization of debt discount and issuance costs	2,855	—	4,544	—
Total interest expense	$ 4,688	$ —	$ 7,539	$ —

Future minimum payments on our long-term debt as of June 30, 2018 were as follows:

Years ended December 31,	Future Minimum Payments (in thousands)
2018	$ 3,594
2019	7,188
2020	7,188
2021	7,188
2022	7,188
2023 and thereafter	305,466
Total minimum payments	337,812
Less: interest	(50,312)
Less: unamortized discount and issuance costs	(111,448)
Less: current portion	—
2025 convertible senior notes, net	$ 176,052

9. Convertible Preferred Stock

On January 7, 2018, the Company entered into a Preferred Stock Purchase Agreement (the "Purchase Agreement") with certain institutional and other accredited investors affiliated with or managed by Redmile Group, LLC (the "Buyers"). Under the terms of the Purchase Agreement, on January 12, 2018, the Company sold to the Buyers in a private placement 725,268 shares of Series A-1 convertible preferred stock at $137.88 per share for net proceeds of approximately $97.7 million, after deducting fees and applicable expenses of $2.3 million. The Buyers hold more than 5% of our capital stock and therefore are considered a related party of the Company. The Purchase Agreement also provided the Company with an option to sell up to $150 million of convertible preferred stock in aggregate beginning after the 90-day period following the date of the initial purchase of the convertible preferred stock. This option was classified as an asset and was determined to have immaterial fair value at inception and subsequently. The Company's right to sell an additional $150 million of convertible preferred stock terminated upon closing of the Convertible Notes on February 1, 2018 (see Note 8) and no additional shares will be issued under the Purchase Agreement, except in the event of warrants issued and exercised as a result of a deemed liquidation event, as described further below. The terms and conditions of the convertible preferred stock are governed by the Certificate of Designation of Preferences, Rights and Limitations (the "Certificate of Designation").

Liquidation preference

In the event of any liquidation, dissolution, or winding up of the Company, whether voluntary or involuntary, occurs within 24 months of the date of the Purchase Agreement, after satisfaction of all liabilities and obligations to creditors of the Company and before any distribution to holders of the Company's common stock, the holders of each share of convertible preferred stock shall be entitled to receive the amount of $137.88 per share, plus all accrued but unpaid dividends. If, upon the occurrence of such event, the proceeds distributed among the holders of the convertible preferred stock are insufficient to make payment in full to all holders, then the entire proceeds legally available for distribution to the holders of the convertible preferred stock shall be distributed ratably in proportion to the full amounts to which the holders would otherwise be respectively entitled. A liquidation shall be deemed to include the occurrence of either (i) the Company merges into or consolidates with any other entity, or any entity merges into or consolidates with the Company and, after giving effect to such transaction, the stockholders of the Company immediately prior to such transaction own less than 50% of the aggregate voting power of the Company or the successor entity of such transaction or (ii) the Company sells, leases, licenses or transfers all or substantially all of its assets to another person or entity and the stockholders of the Company immediately prior to such transaction own less than 50% of the aggregate voting power of the acquiring entity immediately after the transaction (each a "Deemed Liquidation").

Dividends

The holders of the convertible preferred stock are entitled to receive cumulative dividends at a rate of 5% per annum payable semi-annually in arrears on June 30 and December 31 of each year commencing on June 30, 2018. The dividends are payable in additional shares of convertible preferred stock and/or cash at the Company's option. In June 2018, the Company's Board of Directors declared a dividend on the Company's convertible preferred stock to be paid in additional shares and 16,927 additional shares of convertible preferred stock were issued on June 30, 2018, which were recorded at fair value. In the three and six months ended June 30, 2018, the Company accrued an aggregate of $2.3 million and $3.4 million, respectively, in dividends on convertible preferred stock or $3.17 and $4.67 per share of convertible preferred stock.

Conversion

Each share of convertible preferred stock is convertible, at any time and from time to time and after the issuance date, at the holders' option, into shares of common stock in a one-for-ten basis.

Voting Rights

Except specifically required by the Certificate of Designation or by the provisions of the Delaware General Corporation Law, the holders of the convertible preferred stock have no voting rights.

Warrants

In the event of a Deemed Liquidation that occurs within 24 months of the date of the Purchase Agreement, the Company will issue to the Buyers a warrant to purchase an aggregate of 75,000 shares of convertible preferred stock at a purchase price per share equal to the initial purchase price of $137.88. The number of shares and exercise price are each subject to adjustment for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction.

Pursuant to applicable accounting standards, the warrant was considered freestanding financial instrument which is a financial liability and requires initial and subsequent measurements at fair value. The warrant was determined to have immaterial fair value initially and subsequently at June 30, 2018.

In accordance with ASC 480-10-S99, the convertible preferred stock has been recorded as temporary equity on the Company's condensed consolidated balance sheet because the convertible preferred stock is redeemable for cash or other assets of the Company upon Deemed Liquidation events that are not within the control of the Company. The net carrying amount of the convertible preferred

stock is not currently accreted to a redemption value because the preferred stock is not currently redeemable or probable of becoming redeemable in the future.

In accordance with ASC 470-20, the Company recognized a beneficial conversion feature representing a conversion right with an effective conversion price less than the market price of the underlying stock at the commitment date of January 12, 2018. The beneficial conversion feature of $29.5 million was recognized by allocating the intrinsic value of the conversion option, which is the number of shares of common stock available upon conversion multiplied by the difference between the effective conversion price per share and the fair value of common stock per share on the commitment date, to additional paid-in capital. On the last trading day prior to the entering into the Purchase Agreement, the closing price of the Company's common stock was $12.95 per share. The transaction closed on January 12, 2018, at which time last closing price of the Company's common stock was $17.85 per share which is the value used in calculating the intrinsic value of the beneficial conversion feature. Since the convertible preferred stock is currently convertible at holder's option, the Company immediately accreted the full amount of discount created by allocation of proceeds to the beneficial conversion feature and recognized as a deemed dividend to the convertible preferred stockholders.

10. Teva License Agreement

On January 5, 2018, the Company entered into a Settlement and License Agreement with Teva Pharmaceuticals International GmbH ("Teva GmbH"). Under the terms of the Settlement and License Agreement, the Company received a non-exclusive license to Teva's calcitonin gene-related peptide (CGRP) patent portfolio for the development, manufacturing and commercialization of eptinezumab in the U.S. and worldwide, excluding Japan and Korea. While the agreement does not provide the Company with a license for Japan and Korea, the Company believes it has freedom to develop, manufacture and commercialize eptinezumab in these countries.

Upon the execution of the agreement, the Company made an immediate one-time, non-refundable payment of $25 million which was included in research and development expense in the Company's condensed consolidated statement of operations. In addition, a second one-time, non-refundable payment of $25 million is payable upon the approval of a BLA for eptinezumab with the U.S. Food and Drug Administration or of an earlier equivalent filing with a regulatory authority elsewhere in the license territory in which Teva GmbH licensed patents exist. The Company is also obligated to pay $75 million at each of two sales-related milestones (at $1 billion and $2 billion in annual sales) and to provide certain royalty payments on net sales at rates from 5% to 7% following the commercial launch of eptinezumab.

Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This section should be read in conjunction with our unaudited condensed consolidated financial statements and related notes included in Part I, Item 1 of this report and our audited consolidated financial statements and related notes thereto and management's discussion and analysis of financial condition and results of operations for the year ended December 31, 2017 included in our Annual Report on Form 10-K, or 2017 Form 10-K.

Forward-Looking Statements

This discussion contains certain forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements are identified by words such as "believe," "will," "may," "estimate," "continue," "anticipate," "intend," "should," "plan," "expect," "predict," "c or the negative of these terms or similar expressions. You should read these statements carefully because they discuss future expectations, contain projections of future results of operations or financial condition, or state other "forward-looking" information. These statements relate to our future plans, objectives, expectations, intentions and financial performance and the assumptions that underlie these statements. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed in this report in Part II, Item 1A — "Risk Factors," and elsewhere in this report. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. These statements, like all statements in this report, speak only as of their date, and we undertake no obligation to update or revise these statements in light of future developments.

Overview

We are a clinical-stage biopharmaceutical company that discovers, develops and seeks to commercialize therapeutic antibodies with the potential to meaningfully transform the treatment paradigm in migraine. All of our product candidates were discovered and developed by Alder scientists using our proprietary antibody technology platform coupled with a deliberate approach to design and select candidates with properties that we believe optimize the therapeutic potential for patients and commercial competitiveness.

We are focusing our resources and development efforts principally on eptinezumab (ALD403), our most advanced solely-owned product candidate, in order to maximize its therapeutic and commercial potential. Eptinezumab is being evaluated in a pivotal trial program for the prevention of migraine, with a Biologics License Application (BLA) submission to the U.S. Food and Drug Administration (FDA) planned for the first quarter of 2019. Migraine is a serious neurological disease affecting about 36 million people in the United States. Of that number, approximately 13 million people in the United States are candidates for a migraine prevention therapeutic. Of these candidates for migraine prevention, we estimate that there are between five million to seven million people living with episodic and chronic migraine who are the most highly impacted patients, and they typically experience eight or more migraine days per month. Current preventive migraine treatment options available in the market today are challenged by safety, efficacy and tolerability limitations. Epidemiologic studies suggest that approximately 38% of migraineurs would benefit from preventive therapies, but only 11% currently receive them. As a result, we believe there is a significant unmet need for new treatment and prevention options. We plan to focus our initial commercialization efforts for

eptinezumab on the approximately 3,000 headache specialists that see the largest number of these highly impacted patients.

Eptinezumab is a genetically engineered monoclonal antibody inhibiting calcitonin gene-related peptide (CGRP), a small protein and a validated target that is understood to drive migraine initiation, maintenance and chronification. Designed to deliver a competitively differentiated approach to migraine prevention, we believe eptinezumab holds the potential to be a transformative therapeutic and meet a profound medical need, changing the migraine prevention treatment paradigm for physicians and patients living with migraine.

Our deliberate approach to engineering and developing eptinezumab is designed to provide a unique clinical profile that, after a single administration via an infusion procedure, provides rapid, effective and sustained migraine prevention. We believe that this clinical profile, as supported by data from our clinical trials, will present a potentially compelling value proposition for patients, physicians, payors and our stakeholders.

Eptinezumab is the only potent and selective anti-CGRP monoclonal antibody in clinical development delivered by infusion. We believe that eptinezumab's design, coupled with the infusion mode of administration, provides the following key benefits:

- High specificity and strong binding for rapid and sustained suppression of CGRP biology;
- Allows for the total dose to be immediately active to inhibit CGRP with 100% bioavailability; and

- Supervised medication administration has the potential to promote patient adherence while maximizing product control and consistency of delivery.

In our first Phase 3 pivotal trial, PRevention Of Migraine via Intravenous ALD403 Safety and Efficacy 1 (PROMISE 1) for the prevention of frequent episodic migraine, and our second Phase 3 pivotal trial, PRevention Of Migraine via Intravenous ALD403 Safety and Efficacy 2 (PROMISE 2) for the prevention of chronic migraine, eptinezumab has demonstrated:

1. Rapid: Suppression of migraine risk is achieved on the first day post infusion:
- On Day 1 post infusion, the risk of having a migraine was reduced by >50% versus baseline following a single administration
2. Effective: Significant days of migraine freedom attained within 1 month following a single administration
- Approximately 1 in 3 patients had a ≥75% reduction in migraine days within 1 month
- More than half of patients had a ≥50% reduction in migraine days within 1 month
3. Sustained: Migraine free days sustained for 3 months following a single administration
- ≥50% and ≥75% reductions in migraine days sustained through 3 months
- Average 15-17% of patients had no migraines for months 1 to 3
4. Safety and tolerability profile consistent with earlier eptinezumab studies

We plan to submit a BLA to the FDA for eptinezumab in the first quarter of 2019. The pivotal trial program, in support of our BLA submission, consists of PROMISE 1, PROMISE 2 and a single open-label Phase 3 safety clinical trial. PROMISE 1 commenced in October 2015 and is evaluating the safety and efficacy of eptinezumab once every 3 months for one year in 888 patients with episodic migraine, defined as four to 14 migraine days per month. PROMISE 2 commenced in November 2016 and is evaluating the safety and efficacy of eptinezumab once every 3 months for 6 months in 1,072 patients with chronic migraine, defined as 15 or more headache days per month, with diagnostic and therapeutic features of migraine being present on eight or more days per month. The open-label trial commenced in December 2016 and is evaluating the long-term safety and tolerability of eptinezumab once every 3 months in approximately 120 patients with chronic migraine. On June 27, 2017, we announced top-line results from PROMISE 1, showing that eptinezumab met the primary and key secondary endpoints. On January 8, 2018, we announced top-line results from PROMISE 2, showing that eptinezumab met all primary and key secondary endpoints. We recently completed one year of dosing in the open-label trial, generating the required one-year (i.e., four quarterly doses) data for our BLA submission. The safety profile in this trial to date is consistent with previous eptinezumab trials, and we have elected to extend the trial for another year. We are also focused on executing key chemistry, manufacturing and controls, or CMC, activities supporting our BLA submission, including a pharmacokinetic comparability study to be completed in the second half of 2018.

Assuming eptinezumab administered via infusion is approved by the FDA, we plan to focus our initial commercialization efforts on procedure oriented headache specialists in the United States with a specialty sales force sizing of approximately 75 to 125. We believe that these headache specialists comprise neurologists, pain specialists and primary care physicians and treat the highest proportion of the five million to seven million highly impacted migraine patients described above. We estimate this group of headache specialists to number approximately 3,000 physicians. We believe many of these physicians have a stronger preference for eptinezumab delivered via infusion versus self-administered anti-CGRP options due to the strength of eptinezumab’s clinical profile. They also value patient adherence benefits associated with supervised medication administration and they have an infrastructure in place for patient flow, supply and reimbursement. We estimate that 94% of these physicians have previously prescribed an infusion therapy for migraine or other conditions within practice, hospital, or free-standing infusion centers.

We are committed to commercializing eptinezumab in the United States as a migraine prevention therapy, and are focused on capturing the full commercial value of eptinezumab globally. We recognize the potential for strategic

partnerships or other arrangements that bring additional capabilities and infrastructure, as well as value to the program. Our current plans and activities are centered on the planned eptinezumab BLA submission, preparing for commercial drug supply and our own initial commercialization readiness efforts in the United States. We will only pursue partnerships or arrangements at a time and on such terms that we believe have the potential to deliver the greatest value to the eptinezumab program and our stakeholders.

Our product candidate pipeline also includes ALD1910, a preclinical monoclonal antibody that targets pituitary adenylate cyclase-activating polypeptide-38 (PACAP-38). ALD1910 is undergoing investigational new drug (IND)-enabling studies for the prevention of migraine. PACAP-38 is a protein that is active in mediating the initiation of migraine, and we believe that ALD1910 holds potential as a treatment for migraineurs who have an inadequate response to therapeutics directed at CGRP or its receptor. Our third pipeline candidate is clazakizumab, designed to block the pro-inflammatory cytokine IL-6. In May 2016, we licensed the exclusive worldwide rights for clazakizumab to Vitaeris, Inc., or Vitaeris, based in Vancouver, British Columbia. In November 2017 Alder and Vitaeris amended the license agreement for clazakizumab and Vitaeris and its shareholders, including Alder, entered into a strategic collaboration and purchase option agreement (the “option agreement”) with a third party, CSL Limited (CSL), an Australian entity, to expedite the development of clazakizumab as a therapeutic option for solid organ transplant rejection. Prior to the license to

Vitaeris, clazakizumab completed two positive Phase 2b clinical trials establishing proof-of-concept in patients with rheumatoid arthritis.

We were incorporated in 2002 and have not generated any product revenue. We have funded our operations primarily through sales of our equity securities, debt securities and payments from our former collaboration partners. We are focusing our resources and development efforts principally on eptinezumab in order to maximize its therapeutic and commercial potential.

Recent Developments

Appointment of Robert W. Azelby as President and Chief Executive Officer

Effective June 13, 2018, Robert W. Azelby was appointed to serve as our President and Chief Executive Officer and as a member of our Board of Directors. Mr. Azelby succeeded Paul B. Cleveland, a member of our Board of Directors who served as our Interim President and Chief Executive Officer since March 15, 2018. Mr. Cleveland continues to serve as a member of our Board of Directors.

Eptinezumab Data Presentations at American Headache Society 60th Annual Scientific Meeting

In June 2018, we presented updated data from PROMISE 1 and PROMISE 2 at the American Headache Society 60th Annual Scientific Meeting, including year-long efficacy data from PROMISE 1 and six-month efficacy data from PROMISE 2 for chronic migraine patients who received two quarterly infusions of eptinezumab. The data demonstrated further numerical improvement in efficacy with subsequent infusions in both pivotal trials, reinforcing the clinical profile demonstrated by our earlier data, as well as our belief that eptinezumab, if approved, has the potential to be an important treatment option for physicians and patients living with migraine.

PROMISE 1 Data Highlights

After the first quarterly infusion, patients with episodic migraine treated with 300mg or 100mg of eptinezumab experienced 4.3 and 3.9 fewer monthly migraine days (MMDs), from a baseline of 8.5 MMDs, compared to 3.2 fewer MMDs for placebo-treated patients (p value = 0.0001 for 300mg and 0.0182 for 100mg). At one year after the third and fourth quarterly infusions, patients treated with 300mg or 100mg of eptinezumab experienced further gains in efficacy with 5.2 and 4.6 fewer MMDs, respectively, from baseline compared to 4.0 fewer MMDs for placebo-treated patients.

Each month, on average, 31 percent and 27 percent of patients with episodic migraine treated with 300mg or 100mg of eptinezumab, respectively, achieved a 100 percent reduction of MMDs (migraine freedom) over the 6 months after the third and fourth quarterly infusions compared to 21 percent of placebo-treated patients.

At one year after the third and fourth infusions, 69 percent and 65 percent of patients treated with 300mg or 100mg of eptinezumab, respectively, achieved 50 percent or greater reduction of MMDs from baseline over a full 3 months, compared to 56 percent for placebo; and 48 percent and 41 percent of patients treated with 300mg or 100mg of eptinezumab, respectively, achieved 75 percent or greater reduction of MMDs from baseline over a full 3 months, compared to 32 percent for placebo.

The safety profile for eptinezumab across all 4 quarterly infusions observed in PROMISE 1 was consistent with previously reported eptinezumab clinical trials. There were no new safety findings. The percentages of patients with

any adverse event were similar across the eptinezumab and placebo treatment groups. The most commonly reported adverse events occurring at an incidence of 2.0 percent or greater across all eptinezumab groups and greater than placebo were: upper respiratory tract infection (10.5 vs 7.2 percent), nasopharyngitis (common cold) (6.8 vs 5.4 percent), fatigue (3.2 vs <1.0 percent), diarrhea (2.3 vs 1.4 percent) and oropharyngeal (mouth/throat) pain (2.0 vs <1.0 percent).

PROMISE 2 Data Highlights

After the first quarterly infusion, patients with chronic migraine treated with 300mg or 100mg of eptinezumab experienced 8.2 and 7.7 fewer MMDs, respectively, from a baseline of 16 MMDs, compared to 5.6 fewer MMDs for placebo-treated patients (p value < 0.0001 for both dose levels). A further reduction in MMDs was seen after a second quarterly infusion; 8.8 and 8.2 fewer MMDs for patients treated with 300mg and 100mg of eptinezumab, respectively, compared to 6.2 fewer MMDs for placebo-treated patients.

Each month, on average, 21 percent and 18 percent of patients with chronic migraine treated with 300mg or 100mg of eptinezumab, respectively, achieved a 100 percent reduction of MMDs (migraine freedom) over the 3 months after the second quarterly infusion compared to 9 percent of placebo-treated patients.

After the second quarterly infusion, 64 percent and 61 percent of patients treated with 300mg or 100mg of eptinezumab, respectively, achieved a 50 percent or greater reduction of MMDs from baseline, compared to 44 percent for placebo; and 43 percent and 39 percent of patients treated with 300mg or 100mg of eptinezumab, respectively, achieved a 75 percent or greater reduction of MMDs from baseline, compared to 24 percent for placebo-treated patients.

The safety profile for eptinezumab across both quarterly doses observed in PROMISE 2, was consistent with previously reported eptinezumab clinical trials. There were no new safety findings. The percentages of patients with any adverse event were similar across the eptinezumab and placebo treatment groups. The most commonly reported adverse events occurring at an incidence

of 2.0 percent or greater across all eptinezumab groups and greater than placebo were: nasopharyngitis (common cold) (7.4 vs 6.0 percent), urinary tract infection (2.8 vs 1.6 percent), nausea (2.5 vs 1.9 percent), arthralgia (2.3 vs <1.0 percent), dizziness (2.0 vs 1.1 percent) and fatigue (2.0 vs 1.9 percent).

Financial Operations Overview

Revenues and Cost of Sales

We did not recognize any revenue or cost of sales for the three and six months ended June 30, 2018. We recognized $0.7 million in revenue and $0.7 million in cost of sales for the three and six months ended June 30, 2017. We have not generated any revenues from the sale of products. In the future, we may generate revenues from product sales and from collaboration agreements in the form of license fees, milestone payments, reimbursements for clinical supply and development costs and royalties on product sales. We expect that any revenues we generate will fluctuate from quarter to quarter as a result of the uncertain timing and amount of such payments and sales.

Research and Development Expenses

Research and development expenses represent costs incurred by us for the discovery and development of our product candidates. The following items are included in research and development expenses:

- external costs under agreements with clinical research organizations, or CROs, contract manufacturing organizations, or CMOs, and other significant third-party vendors or consultants used to perform preclinical, clinical, medical affairs and manufacturing activities;
- internal costs including employee-related costs such as salaries, benefits, stock-based compensation expense, travel, laboratory consumables and services for our research and development personnel; and
- allocated facilities, depreciation, and other expenses, which include rent and maintenance of facilities, information technology services and other infrastructure expenses.

We use our employee and infrastructure resources across multiple research and development programs directed toward evaluating our monoclonal antibodies for selecting product candidates. We manage certain activities such as preclinical toxicology studies, clinical trial operations and manufacture of product candidates through third-party CROs, CMOs or other third-party vendors. We track our significant external costs by each product candidate. We also track our human resource efforts on certain programs for purposes of billing our collaborators for time incurred at agreed upon rates. We do not, however, assign or allocate to individual product candidates or development programs our internal costs and we group these internal research and development activities into three categories:

Category	Description
Preclinical discovery and development	Research and development expenses incurred in activities substantially in support of discovery of new targets through the selection of a single product candidate. These activities encompass the discovery and translational medicine functions, including pharmacokinetic and drug metabolism preclinical studies, toxicology and early strain and assay development activities.
Pharmaceutical operations	Research and development expenses incurred related to manufacturing preclinical study and clinical trial materials, including scale-up process development and quality control activities.
Clinical development	Research and development expenses incurred related to Phase 1, Phase 2 and Phase 3 clinical trials, including regulatory and medical affairs activities.

We plan to increase our research and development expenses for the foreseeable future as we continue the development of eptinezumab, ramp up our manufacturing activities in preparation for commercial drug supply, continue to develop our medical affairs capability, continue to prepare for regulatory submissions and advance the ALD1910 program. The timing and amount of research and development expenses incurred will depend largely upon the outcomes of current and future clinical trials for our product candidates as well as the related regulatory requirements, manufacturing costs and any costs associated with the advancement of our preclinical programs. We cannot determine with certainty the duration and completion costs of the current or future clinical trials of our product candidates. The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors, including:

- the scope, rate of progress, and expense of our ongoing, as well as any additional, clinical trials and other research and development activities;
- future clinical trial results;
- potential changes in government regulation;
- potential changes in the reimbursement landscape; and
- the timing and receipt of any regulatory approvals.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related benefits, including stock-based compensation, related to our executive, business development, intellectual property, finance, human resources, marketing and support functions. Other general and administrative expenses include allocated facility-related costs not otherwise included in research and development expenses, travel expenses and professional fees for marketing, auditing, tax and legal services, including intellectual property related legal services. We expect our general and administrative costs will continue to rise in 2018 as we increase our headcount and expand our support staffing, build commercial infrastructure including information technology systems and personnel support for the commercial organization, and other activities to support our growth as we prepare for a potential commercial launch of eptinezumab.

Other Income (Expense)

Other income (expense) consists primarily of interest income received on our cash, cash equivalents, investments, and restricted cash, interest expense on the 2.5% Convertible Senior Notes due 2025, or the Convertible Notes, gains and losses on foreign currency, refundable Australian tax credits received by our wholly-owned Australian subsidiary, and the change in fair value of the derivative liability on our investment in Vitaeris. We anticipate other expenses to increase due to interest expense on the Convertible Notes.

Results of Operations

Comparison of the Three and Six Months Ended June 30, 2018 and 2017

Revenue

We did not recognize any revenue for the three and six months ended June 30, 2018. We recognized $0.7 million in revenue and $0.7 million in cost of sales in the three and six months ended June 30, 2017 related to the sale of drug supply inventory to Vitaeris at cost.

Research and Development Expenses

Research and development expenses incurred in the three and six months ended June 30, 2018 and 2017 were as follows:

	Three Months Ended June 30,			Six Months Ended June 30,		
	2018	2017	% change	2018	2017	% change
	(dollars in thousands)			(dollars in thousands)		
External costs:						
Eptinezumab	$31,785	$48,561	(35 %)	$84,902	$123,264	(31 %)
ALD1910	618	937	(34 %)	3,985	1,596	150 %
Unallocated internal costs:						
Preclinical discovery and development	4,955	5,230	(5 %)	9,831	10,387	(5 %)
Pharmaceutical operations	7,059	5,761	23 %	13,762	11,551	19 %
Clinical development	8,401	4,787	75 %	14,386	9,167	57 %
Total research and development expenses	$52,818	$65,276	(19 %)	$126,866	$155,965	(19 %)

Research and development expenses decreased by $12.5 million, or 19%, for the three months ended June 30, 2018 compared to the same period in 2017. During the three months ended June 30, 2018, external costs incurred for eptinezumab decreased by $16.8 million, or 35%. External costs for eptinezumab clinical trial expenses decreased $18.3 million due to the completion of patient treatments for several of our clinical trials, offset by an increase of $1.5 million in manufacturing costs. We expect our manufacturing costs to increase in subsequent quarters in preparation for commercial supply. Unallocated internal costs increased by $4.6 million primarily due to an increase of $2.8 million in professional fees to support our commercial development and due to an increase of $1.2 million in compensation as a result of increased headcount.

Research and development expenses decreased by $29.1 million, or 19%, for the six months ended June 30, 2018 compared to the same period in 2017. During the six months ended June 30, 2018, external costs incurred for eptinezumab decreased by $38.4 million, or 31%. The level of spending for eptinezumab decreased primarily by $43.7 million related to manufacturing costs, a decrease of $19.6 million in the costs of on-going clinical trials due to the completion of patient treatments for several of our clinical trials, and offset by the initial payment of $25.0 million to

Teva GmbH under our settlement and license agreement. The decrease in manufacturing costs was driven by timing of expenses, which can fluctuate from quarter to quarter. We expect our manufacturing costs to increase in subsequent quarters in preparation for commercial supply. External costs incurred for ALD1910 increased by $2.4 million as we continued to advance the program. Unallocated internal costs increased by $6.9 million primarily due to an increase of $3.9 million in professional fees to support our ongoing commercial development and compensation expenses increased $2.2 million related to increased headcount.

General and Administrative Expenses

General and administrative expenses increased by $2.6 million, or 27%, for the three months ended June 30, 2018 compared to the same period of 2017. The increase was primarily related to $1.0 million in stock-based compensation due to an increase in headcount and an increase of $1.1 million in general services, primarily related to activities to support commercial readiness activities.

General and administrative expenses increased by $4.3 million, or 22%, for the six months ended June 30, 2018 compared to the same period of 2017. The increase was primarily related to an increase of $2.8 million in compensation and an increase of $1.2 million in stock-based compensation due to an increase in headcount and severance expense and an increase of $1.4 million in general services to support our commercial readiness, offset by a decrease of $1.5 million in consulting expense.

Interest Income

The increase in interest income for the three and six months ended June 30, 2018 was primarily due to higher average balances of cash, cash equivalents and investments compared to the same period of 2017.

Foreign Currency Gain (Loss)

We maintain bank accounts denominated in British pounds, Swiss francs, Australian dollars and Euros for purposes of settling certain obligations arising outside the United States. We recognized a net foreign currency gain of $0.2 million and $0.4 in the three and six months ended June 30, 2018, respectively, and a net foreign currency loss of $0.1 million in the same periods of 2017, due primarily to fluctuations in the exchange rates of the British pound relative to the U.S. dollar.

Interest Expense

Interest expense was $4.7 million and $7.5 million for three and six months ended June 30, 2018, respectively, related to the Convertible Notes and the associated accretion of debt discount and issuance costs. There was no interest expense for the three and six months ended June 30, 2017.

Change in Fair Value of Derivative Liability

The change in fair value of derivative liability was $1.5 million for the three and six months ended June 30, 2018 as a result of the strategic collaboration and purchase option agreement with CSL. There was no change in fair value of derivative liability for the three and six months ended June 30, 2017.

Equity in Net Loss of Unconsolidated Entity

The equity in net loss of unconsolidated entity relates to our investment in Vitaeris. We record our share of any loss or income generated by Vitaeris under the equity method of accounting on a three-month lag. In the six months ended June 30, 2018, our share of Vitaeris' net losses exceeded the carrying value of our investment, and we suspended recognizing additional losses. We did not recognize any equity in net loss for the three months ended June 30, 2018 and we recognized $0.2 million in equity in net loss for the six months ended June 30, 2018. We recognized $0.1 million and $0.3 million in equity in net loss for the three and six months ended June 30, 2017, respectively.

Deemed Dividend on Convertible Preferred Stock Attributable to Accretion of Beneficial Conversion Feature

In January 2018, we completed a private placement of 725,268 shares of convertible preferred stock with certain institutional and other accredited investors. The deemed dividend of $29.5 million relates to the accretion of the beneficial conversion feature which is the difference between the effective conversion price and the fair value of our common stock, which was the closing trading price on the closing date of the offering, multiplied by the number of shares of common stock into which the preferred stock was initially convertible.

Dividends on Convertible Preferred Stock

Holders of the convertible preferred stock are entitled to receive cumulative dividends at a rate of 5% per annum payable semi-annually in arrears on June 30 and December 31 of each year, commencing on June 30, 2018, payable in additional shares of convertible preferred stock and/or cash at our option.

On June 14, 2018, the Company’s board of directors declared dividends on the convertible preferred stock, payable on June 29, 2018. At our option and as permitted by the Certificate of Designation of Preferences, Rights and Limitations, or the Certificate of Designation, dividends were paid in the form of 16,927 shares of preferred stock. In the three and six months ended June 30, 2018, we recorded dividends on preferred stock of $2.3 million and $3.4 million, respectively.

Liquidity and Capital Resources

Due to our significant research and development expenditures, we have generated significant operating losses from inception and we expect to incur significant operating losses in the future. We have funded our operations primarily through sales of our equity securities, debt securities and payments from our former collaboration partners. As of June 30, 2018, we had an accumulated deficit of $822.9 million and cash, cash equivalents and investments of $526.1 million, consisting of cash, money market funds and U.S. government agency obligations, and restricted cash of $10.0 million. In January 2018, we completed a private placement of 725,268 shares of convertible preferred stock resulting in net proceeds of $97.7 million. In February 2018, we received $277.7 million in net proceeds from an underwritten public offering of the Convertible Notes. The purchase agreement for the placement of the convertible preferred stock, including a right we had under such agreement to sell to the investors an additional $150.0 million of convertible

preferred stock, terminated upon the closing of the Convertible Notes offering and no additional shares will be issued under such agreement, except in the event of warrants issued and exercised as a result of a deemed liquidation event. Cash in excess of immediate requirements is invested with a view toward liquidity and capital preservation, and we seek to minimize the potential effects of concentration and degrees of risk.

We are focusing our resources and development efforts principally on eptinezumab in order to maximize its therapeutic and commercial potential. We believe that our available cash, cash equivalents and short-term and long-term investments and restricted cash as of June 30, 2018 will be sufficient to meet our projected operating requirements into 2020. These operating requirements consist principally of expenditures related to the planned BLA submission, establishment of the eptinezumab commercial drug supply chain, continued build-out of our commercial organization (e.g., marketing, sales, medical affairs, payor access, information technology) and pre-launch market readiness. We have based our estimate on the timing for our projected expenditures on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. We will need additional funding to execute the commercial launch of eptinezumab. Furthermore, our operating plans may change, and we may need additional funds to meet operational needs and capital requirements for product development and commercialization of eptinezumab sooner than planned. We will also need to obtain substantial additional sources of funding to develop and commercialize ALD1910 and our other product candidates. We expect to finance future cash needs through equity financings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements, but there are no assurances that we will be able to raise sufficient amounts of funding in the future on acceptable terms, or at all. We currently have no credit facility or committed sources of capital. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates and the extent to which we may enter into additional collaborations with third parties to participate in their development and commercialization, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials or with commercialization of our product candidates. Our future funding requirements will depend on many factors, as we:

- continue to prioritize the advancing clinical development of eptinezumab for the prevention of migraine;
- leverage the commercial potential of eptinezumab by commercializing it for the prevention of migraine in the United States, if approved by the FDA;
- advance the ALD1910 program;
- establish a sales, marketing and distribution infrastructure and scale-up manufacturing capabilities to commercialize eptinezumab or any of our future product candidates if they receive regulatory approval;
- enhance operational, financial and information management systems and hire additional personnel, including personnel to support development of our product candidates and, if a product candidate is approved, our commercialization efforts.
- leverage our technology platform to discover future product candidates for areas of unmet need; and
- build a leading biopharmaceutical company to transform current treatment paradigms.

There are no assurances that we will be able to raise sufficient amounts of funding in the future on acceptable terms, or at all. The sale of additional equity would result in dilution to our stockholders. The incurrence of debt financings would result in debt service obligations and the instruments governing such debt could provide for operating and financing covenants that would restrict our operations. We may consider partnering one or more of our product candidates for further clinical development and commercialization. To the extent that we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us.

Historical Cash Flow Trends

The following table summarizes our cash flows for the periods indicated:

	Six Months Ended June 30,	
	2018	2017
	(in thousands)	
Net cash used in operating activities	$(126,526)	$(126,254)
Net cash provided by (used in) investing activities	(211,124)	137,113
Net cash provided by financing activities	376,508	714

Cash Used in Operating Activities

Net cash used in operating activities includes net loss, adjusted for non-cash charges and changes in the components of working capital. Net cash used in operating activities was $126.5 million in the six months ended June 30, 2018 compared to $126.3 million during the same period in 2017. Although there was a decrease of $19.5 million in net loss in the 2018 period compared to the same period of 2017, this was offset by a decrease in the change in prepaid expense and other assets of $23.8 million, primarily related to prepaid manufacturing expenses. Other non-cash adjustments included the accretion of discount on convertible notes of $4.5 million, and an increase in stock-based compensation of $2.3 million and the non-cash expense of $1.5 million related to the change in fair value of the derivative liability, as well as other changes in components of working capital.

Cash Provided by (Used in) Investing Activities

Net cash used in investing activities was $211.1 million in the six months ended June 30, 2018, compared to net cash provided by investing activities of $137.1 million during the same period in 2017. The decrease of $348.2 million in net cash used by investing activities was primarily due to an increase in purchases of investments offset by proceeds of maturities and sales of investments. In addition, purchases of equipment decreased by $1.2 million in the six months ended June 30, 2018 compared to the same period in 2017.

Cash Provided by Financing Activities

Net cash provided by financing activities was $376.5 million in the six months ended June 30, 2018 was primarily due to the January 2018 issuance of convertible preferred stock and the February 2018 issuance of the Convertible Notes in which we received proceeds of $97.7 million and $277.7 million, respectively, net of offering costs. Net cash provided by financing activities in the six months ended June 30, 2017 was due to the exercise of stock options and purchases under the employee stock purchase plan.

Off-Balance Sheet Arrangements

We did not have any off-balance sheet arrangements as of June 30, 2018.

Contractual Obligations

Our contractual obligations as of June 30, 2018 were as follows:

		For the years ended June 30,					
	Total	2019	2020	2021	2022	2023	Thereafter
	(in thousands)						
Convertible debt obligation[1]	$337,812	$7,188	$7,188	$7,188	$7,188	$7,188	$301,872
Operating lease obligations[2]	7,588	1,359	1,460	1,499	1,544	1,591	135
License agreements[3]	715	60	60	60	60	60	415
Purchase obligations[4]	12,222	12,222	—	—	—	—	—
Contract manufacturing obligations[5]	193,260	73,515	47,600	36,033	36,112	—	—
Total contractual obligations	$551,597	$94,344	$56,308	$44,780	$44,904	$8,839	$302,422

(1) Represents future minimum payments of interest and principal under the Convertible Notes.
(2) Represents future minimum lease payments under our non-cancelable operating leases. The minimum lease payments above do not include any related common area maintenance charges or real estate taxes.
(3) Some of our licensing agreements obligate us to pay a royalty on net sales of products utilizing licensed technology. Such royalties are dependent on future product sales and are not provided for in the table above as they are not estimable.
(4) We enter into agreements in the normal course of business with contract research organizations for clinical trials and with vendors for preclinical research studies and other services and products for operating purposes which are cancelable at any time by us, generally upon 30 days prior written notice. These payments are not included in this table of contractual obligations.
(5) Represents contractual obligations related to manufacturing our product candidates for use in our clinical trials, including long-term stability studies. Includes estimated purchase obligations as of June 30, 2018 under agreements with third-party contract manufacturing organizations for larger scale production of eptinezumab. This includes obligations for which we have placed $10.0 million in an escrow account which is classified as restricted cash on our condensed consolidated balance sheet. We expect to incur additional purchase obligations relating to future purchase orders under such agreements.

Certain contract manufacturing obligations may be cancelled 18 to 24 months prior to the commencement date of the manufacturing campaign. Although the payment of the cancellation fee will generally be due at the scheduled commencement date, we may record the manufacturing expense and related obligation as an accrued liability at the time of cancellation.

The holders of our convertible preferred stock are entitled to receive cumulative dividends at a rate of 5% per annum payable semi-annually in arrears on June 30 and December 31 of each year commencing on June 30, 2018, in additional shares of convertible preferred stock and/or cash at our option. Based on the 725,268 shares of convertible preferred stock issued and outstanding as of June 30, 2018, this equated to $2.3 million in cash or 16,927 shares of additional convertible preferred stock to be issued in lieu of cash on June 30, 2018 and at each future dividend payment date excluding the impact of compounding due to new shares being issued. On June 14, 2018, our board of directors declared a dividend on the convertible preferred stock, payable on June 29, 2018. At our option and as

permitted by the Certificate of Designation, dividends were paid in the form of 16,927 shares of preferred stock. We recorded the paid-in-kind dividends at the fair value of $3.4 million on the date of issuance. We currently anticipate settling future dividends by the issuance of additional shares of convertible preferred stock.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with United States general accepted accounting principles, or GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues generated and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

On January 1, 2018, we adopted Topic 606 - "Revenue from Contracts with Customers" and related pronouncements regarding revenue recognition. For a discussion of our revenue recognition policies, please see Note 2 to our condensed consolidated financial statements, which are included in this report. There have been no other significant and material changes in our critical accounting policies during the six months ended June 30, 2018, as compared to those disclosed in "Management's Discussion and Analysis of Financial Conditions and Results of Operations - Critical Accounting Policies and Significant Judgments and Estimates" in our 2017 Form 10-K. We believe that the accounting policies discussed in our 2017 Form 10-K are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Recent Accounting Pronouncements

For a discussion of recent accounting pronouncements, please see Note 2 to our condensed consolidated financial statements, which are included in this report.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Risk

The primary objective of our investment activities is to preserve our capital to fund our operations. We also seek to maximize income from our investments without assuming significant risk. To achieve our objectives, we maintain a portfolio of cash equivalents and investments in a variety of securities of high credit quality. As of June 30, 2018, we had cash, cash equivalents, short-term and long-term investments and restricted cash of $536.1 million consisting of cash, money market funds, and U.S. government agency obligations. A portion of our investments may be subject to interest rate risk and could fall in value if market interest rates increase. We have estimated the effect on our investment portfolio of a hypothetical increase in interest rates by one percent to be a reduction of $3.4 million in the fair value of our investments as of June 30, 2018. In addition, a hypothetical decrease of 10% in the effective yield of our investments would reduce our expected investment income by approximately $0.9 million over the next twelve months based on our investment balance at June 30, 2018.

Foreign Currency Risk

We contract for the conduct of certain clinical development activities with vendors in Australia and we contract for the conduct of manufacturing activities in the United Kingdom, Switzerland and Austria. Our foreign subsidiaries in Australia and Ireland also maintain bank accounts in their local currencies which are Australian dollars and Euros. We are subject to exposure due to fluctuations in foreign exchange rates in connection with these currencies. We manage a portion of these cash flow exposures through our bank accounts in which we hold foreign currencies. Our holdings in foreign currencies are marked to market at the end of each period and any net change is recorded as gains or losses in the condensed consolidated statements of operations. As of June 30, 2018, we held the U.S. dollar equivalent of approximately $0.8 million in foreign currencies. A hypothetical 10% change in the exchange rate between the U.S. dollar and Swiss francs, Australian dollars, and Euros from the June 30, 2018 rate would have increased/decreased our total unrealized foreign currency loss on our holdings by approximately $0.1 million. We generally transfer funds to our Australian subsidiary and our Irish subsidiary to fund operating needs within 30 days of disbursement and these cash balances are also subject to exposure due to fluctuations in exchange rates. For the three and six months ended June 30, 2018, we recorded net foreign currency gains of $0.2 million and $0.4 million, respectively. For the three and six months ended June 30, 2017, our net foreign currency losses were $0.1 million in both periods.

Item 4. Controls and Procedures

Evaluation of disclosure controls and procedures. Our management, with the participation of our Chief Executive Officer and our Executive Vice President and Principal Accounting Officer, our principal financial officer, have evaluated 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) prior to the filing of this quarterly report. Based on that evaluation, our Chief Executive Officer and our Executive Vice President and Principal Accounting Officer, have concluded that, as of the end of the period covered by this quarterly report, our disclosure controls and procedures were, in design and operation, effective.

Changes in internal control over financial reporting. There were no changes in our internal control over financial reporting during the quarter ended June 30, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Because of inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

PART II. – OTHER INFORMATION

Item 1. Legal Proceedings

There were no material changes with respect to the matters disclosed in “Item 3. Legal Proceedings” in our 2017 Form 10-K during the period covered by this report.

Item 1A. Risk Factors

You should carefully consider the following risk factors, in addition to the other information contained in this report on Form 10-Q, including the section of this report titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our financial statements and related notes. If any of the events described in the following risk factors and the risks described elsewhere in this report occurs, our business, operating results and financial condition could be seriously harmed. This report on Form 10-Q also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this report.

Risks Related to Our Need for Additional Financing and Our Financial Results

We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future.

We are a clinical-stage biopharmaceutical company. We do not currently have any products approved for sale, and we continue to incur significant research and development and general and administrative expenses. We have incurred significant operating losses in the past and expect to incur substantial and increasing losses for the foreseeable future. For the six months ended June 30, 2018, our net loss applicable to common stockholders was $188.3 million, and as of June 30, 2018, we had an accumulated deficit of $822.9 million.

To date, we have devoted substantially all of our efforts to research and development, including clinical trials, but have not completed development or commercialized any product candidates. We anticipate that our expenses will increase substantially as we:

- continue the research and development of eptinezumab, ALD1910 and our other product candidates;
- seek regulatory approvals for our product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure and scale-up manufacturing capabilities to commercialize eptinezumab or any of our future product candidates if they receive regulatory approval; and

- enhance operational, financial and information management systems and hire additional personnel, including personnel to support development of our product candidates and, if a product candidate is approved, our commercialization efforts.

To be profitable in the future, we and any of our future collaborators must succeed in developing and eventually commercializing products with significant market potential. This will require success in a range of activities, including advancing product candidates, completing clinical trials of product candidates, obtaining regulatory approval and reimbursement coverage for these product candidates and manufacturing, marketing and selling those products for which regulatory approval is obtained. We are only in the preliminary stages of some of these activities. We and any of our future collaborators may not succeed in these activities and may never generate revenues that are sufficient to be profitable in the future.

Drug development is a highly speculative undertaking and involves a substantial degree of uncertainty. We have never generated any revenues from product sales and may never be profitable.

We have devoted substantially all of our financial resources and efforts to developing our technology platform, identifying product candidates and conducting preclinical studies and clinical trials for our product candidates. We have not completed the development of any products and eptinezumab is our only product candidate in the clinical stage of development. We have never generated revenues from the sale of any products.

Our ability to generate revenues and achieve profitability depends in large part on our ability, on our own or with any of our future collaborators, to successfully complete the development of, obtain the necessary regulatory approvals for, and commercialize our product candidates. We do not anticipate generating revenues from sales of products for several years, if at all. Our ability to generate future revenues from product sales depends on our and any of our future collaborators' success in:

- completing clinical development and obtaining regulatory approval for eptinezumab;

- entering into collaboration agreements with third parties with respect to eptinezumab, ALD1910 or our other product candidates for their development and commercialization in the United States or in international markets, and the continued financial and other support of these third parties under such collaboration agreements;

- launching and commercializing eptinezumab, if approved, and successfully establishing sales, marketing and distribution infrastructure;

- achieving a continued acceptable safety profile of the product following approval;

- achieving a favorable cost of goods sold;

- effectively competing with other therapies, including capturing market share;

- obtaining regulatory approvals for ALD1910 or any future product candidates that we discover and successfully develop;

- establishing and maintaining supply and manufacturing relationships with third parties;

- obtaining coverage and adequate reimbursement from third-party payors; and

- maintaining, protecting, expanding and enforcing our intellectual property, including intellectual property we license from third parties.

Because of the numerous risks and uncertainties associated with biologic product development, we are unable to predict the timing or amount of increased expenses and when we will be able to achieve or maintain profitability, if ever. In addition, our expenses could increase beyond expectations if we are required by the U.S. Food and Drug Administration, or FDA, or foreign regulatory agencies, to perform studies and trials in addition to those that we currently anticipate, or if there are any delays in our or any of our future collaborators' clinical trials or the development of any of our product candidates. If one or more of the product candidates that we independently develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing such product candidates.

We will need additional funds to support our operations, and such funding may not be available to us on acceptable terms, or at all, which would force us to delay, reduce or suspend our research and development programs and other operations or commercialization efforts.

We are primarily focused on the advancement of eptinezumab through the clinical development process to a commercial launch, as well as the advancement of the ALD1910 program and future product candidates. The completion of the development and the potential commercialization of our product candidates, should they receive regulatory approval, will require substantial funds.

As of June 30, 2018, we had $526.1 million in cash, cash equivalents and investments, and $10.0 million in restricted cash. We believe that our available cash, cash equivalents, investments and restricted cash as of June 30, 2018 will be sufficient to meet our projected operating requirements into 2020. These operating requirements consist principally of expenditures related to the planned BLA submission, establishment of the eptinezumab commercial drug supply chain, continued build-out of our commercial organization (e.g., marketing, sales, medical affairs, payor access, information technology) and pre-launch market readiness. We have based our estimate on the timing for our projected expenditures on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. We will need additional funding to execute the commercial launch of eptinezumab. Furthermore, our operating plans may change, and we may need additional funds to meet operational needs and capital requirements for product development and commercialization of eptinezumab sooner than planned. We will also need to obtain substantial additional sources of funding to develop and commercialize ALD1910 and our other product candidates.

Our future financing requirements will depend on many factors, some of which are beyond our control, including the following:

- the rate of progress, recruitment and cost of our clinical trials and clinical success for eptinezumab, ALD1910 and any future product candidates;

- the timing of, and costs involved in, seeking and obtaining approvals from the FDA and other regulatory authorities;

- the costs of commercialization activities if any of our product candidates, such as eptinezumab, receive regulatory approval, including sales, marketing and distribution infrastructure;

- the degree and rate of market acceptance of any products launched by us or any of our future collaborators;

- repayment of the Convertible Notes, which mature on February 1, 2025, unless earlier repurchased, redeemed or converted;

- our ability to enter into additional collaboration, licensing, commercialization or other arrangements and the terms and timing of such arrangements; and

- the emergence of competing technologies or other adverse market developments.

Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates and the extent to which we may enter into additional collaborations with third parties to participate in their development and commercialization, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials or with commercialization of our product candidates.

We do not have any material committed external source of funds or other support for our development efforts. Until we can generate sufficient revenues to finance our cash requirements, which we may never do, we expect to finance future cash needs through equity financings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. There are no assurances that we will be able to raise sufficient amounts of funding on acceptable terms, or at all. If we raise additional capital through equity financings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financings, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, buying or selling assets, making capital expenditures or declaring dividends. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us.

Furthermore, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

A failure to raise additional funding or to effectively implement cost reductions could harm our business, results of operations and future prospects.

Our significant level of indebtedness could limit cash flow available for our operations and expose us to risks that could adversely affect our business, financial condition and results of operations.

We incurred significant indebtedness and substantial debt service requirements as a result of our offering of the Convertible Notes in February 2018. In the future, we may incur additional indebtedness, including secured indebtedness, in connection with financing acquisitions, strategic transactions or for other purposes. The indenture

governing the Convertible Notes does not limit the amount of debt that we or our subsidiaries may incur. Our indebtedness increases the risk that we may be unable to generate enough cash to pay amounts due in respect of our indebtedness, including the Convertible Notes.

Our indebtedness could have important consequences to you and significant effects on our business. For example, it could:

- make it more difficult for us to satisfy our debt obligations, including the Convertible Notes;
- increase our vulnerability to general adverse economic and industry conditions;
- require us to dedicate a substantial portion of our cash flow from operations to payments on our indebtedness, thereby reducing the availability of our cash flow to fund working capital, capital expenditures and other general corporate purposes;
- limit our flexibility in planning for, or reacting to, changes in our business, the industry in which we operate or the general economy;
- restrict us from exploiting business opportunities;

- heighten our vulnerability to downturns in our business, our industry or in the general economy, and restrict us from exploiting business opportunities or making acquisitions;

- limit management's discretion in operating our business;

- place us at a competitive disadvantage compared to our competitors that have less indebtedness; and

- limit our availability to borrow additional funds for working capital, capital expenditures, acquisitions, debt service requirements, execution of our business strategy or other general purposes.

In addition, the agreements that may govern any future indebtedness that we may incur may contain financial and other restrictive covenants that will limit our ability to engage in activities that may be in our long-term best interests. Our failure to comply with those covenants could result in an event of default that, if not cured or waived, could result in the acceleration of all of our debt.

We may not be able to generate sufficient cash to service the Convertible Notes and any other debt we may incur, and may be forced to take other actions to satisfy our obligations under our debt, which may not be successful.

Our ability to make scheduled payments on or to refinance our debt obligations, including the Convertible Notes, and to fund future capital expenditures depends on our ability to generate cash in the future and our financial condition and operating performance, which are subject to prevailing economic and competitive conditions and to certain financial, business and other factors beyond our control. We cannot assure you that we will maintain a level of cash flows from operating activities sufficient to permit us to pay the principal, premium, if any, and interest on (as well as any cash due upon conversion of) our debt, including the Convertible Notes.

If our cash flows and capital resources are insufficient to fund our debt service obligations, we may be forced to adopt one or more alternatives, such as reducing or delaying investments and capital expenditures, or to selling assets, seeking additional capital or restructuring or refinancing our debt, including the Convertible Notes. These alternative measures may not be successful and may not permit us to meet our scheduled debt service obligations. If our operating results and available cash are insufficient to meet our debt service obligations, we could face substantial liquidity problems and might be required to dispose of material assets or operations to meet our debt service and other obligations. We may not be able to consummate those dispositions or to obtain the proceeds that we could realize from them, and these proceeds may not be adequate to meet any debt service obligations then due. Further, we may need to refinance all or a portion of our debt on or before maturity, and we cannot assure you that we will be able to refinance any of our debt on commercially reasonable terms or at all.

The accounting method for convertible debt securities that may be settled in cash, such as the Convertible Notes, could have a material effect on our reported financial results.

Pursuant to Accounting Standards Codification Subtopic 470-20, Debt with Conversion and Other Options, which we refer to as ASC 470-20, an entity must separately account for the liability and equity components of the convertible debt instruments (such as the Convertible Notes) that may be settled entirely or partially in cash upon conversion in a manner that reflects the issuer's economic interest cost. The effect of ASC 470-20 on the accounting for the Convertible Notes is that the equity component is required to be included in the additional paid-in capital section of stockholders' equity on our consolidated balance sheet and the value of the equity component would be treated as original issue discount for purposes of accounting for the debt component of the Convertible Notes. As a result, we will be required to record a greater amount of non-cash interest expense in current periods presented as a result of the

amortization of the discounted carrying value of the Convertible Notes to their face amount over the term of the Convertible Notes. We will report greater losses in our financial statements because ASC 470-20 will require interest to include both the current period's amortization of the debt discount and the instrument's coupon interest, which could adversely affect our reported or future financial results, the market price of our common stock and the trading price of the Convertible Notes. In addition, there may be features within the terms that are considered to be an embedded derivative and could be recorded on the balance sheet at fair value as a liability. If it is determined to be an embedded derivative, we will be required to recognize changes in the derivative's fair value from period to period in other income (expense) in our statements of operations.

In addition, under certain circumstances, convertible debt instruments (such as the Convertible Notes) that may be settled entirely or partly in cash are currently accounted for utilizing the treasury stock method, the effect of which is that the shares issuable upon conversion of the Convertible Notes are not included in the calculation of diluted earnings per share except to the extent that the conversion value of the Convertible Notes exceeds their principal amount. Under the treasury stock method, for diluted earnings per share purposes, the transaction is accounted for as if the number of our common stock that would be necessary to settle such excess, if we elected to settle such excess in shares, are issued. We cannot be sure that we will be able to use the treasury stock method or the accounting standards in the future will continue to permit the use of the treasury stock method. If we are unable to use the treasury

stock method in accounting for the shares issuable upon conversion of the Convertible Notes, then our diluted earnings per share would be adversely affected.

The conditional conversion feature of the Convertible Notes, if triggered, may adversely affect our financial condition and operating results.

In the event the conditional conversion feature of the Convertible Notes is triggered, holders of Convertible Notes will be entitled to convert the Convertible Notes at any time during specified periods at their option. If one or more holders elect to convert their Convertible Notes, unless we elect to satisfy our conversion obligation by delivering solely shares of our common stock (other than paying cash in lieu of delivering any fractional share), we would be required to settle a portion or all of our conversion obligation through the payment of cash, which could adversely affect our liquidity. In addition, even if holders do not elect to convert their Notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the Convertible Notes as a current rather than long-term liability, which would result in a material reduction of our net working capital.

Our ability to use our net operating loss and tax credit carryforwards to offset future taxable income may be subject to certain limitations.

As of December 31, 2017, we had U.S. net operating loss carryforwards, or NOLs, of $643.1 million, for which we have recorded a full valuation allowance, which may be used to offset future taxable income. In addition, we have U.S. research and development tax credit carryforwards of $17.9 million. These NOLs and tax credit carryforwards expire in various years beginning in 2024, if not utilized. Utilization of the NOLs and tax credit carryforwards may be subject to an annual limitation due to historical or future ownership change rules pursuant to Sections 382 and 383 of the Internal Revenue Code, or the Code. We performed a section 382 ownership analysis through 2017 and determined that an ownership change occurred in 2015. Based on the analysis performed, however, we do not believe that the Section 382 annual limitation will impact our ability to utilize the tax attributes that existed as of the date of the ownership change in a material manner. If we have experienced an ownership change in the past or will experience an ownership change as a result of future changes in our stock ownership, some of which changes are outside our control, the tax benefits related to the NOLs and tax credit carryforwards may be further limited or lost.

The recently passed comprehensive tax reform legislation could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law new tax legislation, the Tax Cuts and Jobs Act of 2017, or the TCJA, that significantly changes the Code. The TCJA, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Any federal net operating loss carryovers created in 2018 and thereafter will be carried forward indefinitely pursuant to the TCJA. We continue to examine the impact this tax legislation may have on our business. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the TCJA is uncertain and our business and financial condition could be adversely affected. The impact of the TCJA on holders of our notes or common stock is also uncertain and could be adverse.

Risks Related to Eptinezumab and Our Other Product Candidates

If eptinezumab is not successfully commercialized, our business will be harmed.

Eptinezumab is our only product candidate currently in clinical trials. We have invested a significant portion of our efforts and financial resources into the development of eptinezumab to prevent migraines. Our ability to generate revenues from products, which we do not expect to occur for the foreseeable future, if ever, will depend heavily on the successful development, regulatory approval and eventual commercialization of eptinezumab. The success of eptinezumab and our other product candidates will depend on several factors, including the following:

- successful enrollment in, and completion of, clinical trials, including our PROMISE 1, PROMISE 2 and open-label Phase 3 clinical trials and the pharmacokinetic comparability study of our commercial supply of eptinezumab for our initial Biologics License Application, or BLA, submission;

- our ability to reach agreements with the FDA and other regulatory authorities on the appropriate regulatory path for approval for eptinezumab or other product candidates;

- receipt of approvals from the FDA and similar regulatory authorities outside the United States for eptinezumab or other product candidates;

- establishing and maintaining supply and manufacturing relationships with third parties;

- successfully launching sales, marketing and distribution of any product candidate that may be approved, whether alone or in collaboration with others;

- acceptance of any approved product by the medical community, third-party payors and patients and others involved in the reimbursement process, such as the Centers for Medicare and Medicaid Services in the United States and the National Institute of Clinical Excellence in the United Kingdom;

- achieving a favorable cost of goods sold;

- effectively competing with other therapies, including capturing market share;

- achieving a continued acceptable safety profile of the product following approval; and

- obtaining, maintaining, enforcing and defending intellectual property rights and claims, including intellectual property we license from third parties.

If we do not achieve one or more of these factors in a timely manner, or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would harm our business.

If clinical trials of eptinezumab or any of our other product candidates fail to demonstrate safety and efficacy to the satisfaction of the FDA or similar regulatory authorities outside the United States or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

Before obtaining regulatory approval for the sale of eptinezumab or any of our other product candidates, we or any of our future collaborators must conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical trials are expensive, difficult to design and implement, can take many years to complete and are uncertain as to outcome. A failure of one or more of such clinical trials could occur at any stage of evaluation. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results.

In some cases, we utilize novel mechanisms of action to treat diseases that have not previously been addressed by antibody therapies. We or any of our future collaborators may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our or any of our future collaborators' ability to receive regulatory approval or commercialize our product candidates, including the following:

- clinical trials of our product candidates, in particular our PROMISE 1, PROMISE 2 and open-label Phase 3 clinical trials, and the pharmacokinetic comparability study of our commercial supply of eptinezumab for our initial BLA submission, may produce negative or inconclusive results, and we or any of our future collaborators may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;

- the number of patients required for clinical trials of our product candidates may be larger than we or any of our future collaborators anticipate, enrollment in these clinical trials may be insufficient or slower than anticipated or patients may drop out of these clinical trials at a higher rate than anticipated;

- the cost of clinical trials of our product candidates may be greater than anticipated;

- third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us or any of our future collaborators in a timely manner, or at all;

- we or any of our future collaborators might have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding that our product candidates have unanticipated serious side-effects or other unexpected characteristics or that the patients are being exposed to unacceptable health risks;

- regulators may not approve our or any of our future collaborators' proposed clinical development plans;

- regulators or institutional review boards may not authorize us, any of our future collaborators or our investigators to commence a clinical trial or conduct a clinical trial at a prospective site;

- regulators or institutional review boards may require that we, any of our future collaborators or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements; and

- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate.

If we or any of our future collaborators are required to conduct additional clinical trials or other testing of our product candidates beyond those currently contemplated, if we or any of our future collaborators are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we or any of our future collaborators may:

- be delayed in obtaining regulatory approval for our product candidates;

- not obtain regulatory approval at all;

- obtain regulatory approval for indications that are not as broad as intended;

- have the product removed from the market after obtaining regulatory approval;

- be subject to additional post-marketing testing requirements; or

- be subject to restrictions on how the product is distributed or used.

Our product development costs will also increase if we experience delays in testing or approvals. We do not know whether any clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we or any of our future collaborators may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we or any of our future collaborators do, which would impair our or any of our future collaborators' ability to commercialize our product candidates and harm our business and results of operations.

The development and commercialization of biologic products is subject to extensive regulation, and we may not obtain regulatory approvals for eptinezumab or any of our other product candidates.

The clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, import, marketing and distribution and other possible activities relating to eptinezumab, ALD1910 and any other product candidate that we may develop in the future are subject to extensive regulation in the United States. Biologics, like eptinezumab, require the submission of a BLA to the FDA and such product candidates are not permitted to be marketed in the United States until approval from the FDA of a BLA for that product has been obtained. A BLA must be supported by extensive preclinical and clinical data, as well as extensive information regarding chemistry, manufacturing and controls, or CMC, sufficient to demonstrate the safety, purity, potency and effectiveness of the applicable product candidate to the satisfaction of the FDA. We have not submitted an application for approval or obtained FDA approval for any product. This lack of experience may impede our ability to obtain FDA approval in a timely manner, if at all, for eptinezumab, ALD1910 and our future product candidates.

Regulatory approval of a BLA is not guaranteed, and the approval process is an expensive and uncertain process that may take several years. The FDA and foreign regulatory entities also have substantial discretion in the approval process. The number and types of preclinical studies and clinical trials that will be required for BLA approval varies depending on the product candidate, the disease or the condition that the product candidate is designed to target and the regulations applicable to any particular product candidate. Despite the time and expense associated with preclinical studies and clinical trials, failure can occur at any stage, and we could encounter problems that require us to repeat or perform additional preclinical studies or clinical trials or generate additional CMC data. The FDA and similar foreign authorities could delay, limit or deny approval of a product candidate for many reasons, including because they:

- may not deem the product candidate to be adequately safe or effective;

- may not find the data from preclinical studies, clinical trials or CMC data to be sufficient to support a claim of safety and efficacy;

- may not approve the manufacturing processes or facilities associated with the product candidate;

    - may conclude that the long-term stability of the formulation of the drug product for which approval is being sought has been sufficiently demonstrated;

- may change approval policies or adopt new regulations; or

- may not accept a submission due to, among other reasons, the content or formatting of the submission.

To market any biologics outside of the United States, we and any of our future collaborators must comply with the numerous and varying regulatory and compliance related requirements of other countries. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods, including obtaining reimbursement and pricing approval in select markets. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks associated with FDA approval as well as additional, presently unanticipated, risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others, including the risk that our product candidates may not be approved for all indications requested and that such approval may be subject to limitations on the indicated uses for which the product may be marketed.

The results of clinical trials conducted at sites outside the United States may not be accepted by the FDA and the results or clinical trials conducted at sites inside the United States may not be accepted by international regulatory authorities.

We have conducted, and may in the future choose to conduct, our clinical trials outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to certain conditions imposed by the FDA. For example, the clinical trial must be well-designed and conducted and performed by qualified investigators in accordance with ethical principles. The study population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. Generally, the patient population for any clinical trials conducted outside of the United States must be representative of the population for whom we intend to label the product in the United States. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will be dependent upon its determination that the trials also complied with all applicable U.S. laws and regulations. There can be no assurance the FDA will accept data from trials conducted outside of the United States. If the FDA does not accept the data from our international clinical trials, or if international regulatory authorities do not accept the data from our U.S. clinical trials, it would likely result in the need for additional trials, which would be costly and time-consuming and could delay or permanently halt the development of a product candidate.

We face substantial competition, and others may discover, develop or commercialize products before or more successfully than we do.

The development and commercialization of new therapeutic products is highly competitive. We face competition with respect to eptinezumab and our other current product candidates, and will face competition with respect to product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of biosimilar products, which are expected to become available over the coming years. Many of our competitors are large pharmaceutical companies that have a greater ability to reduce prices for their competing drugs in an effort to maintain or gain market share and undermine the value proposition that drugs commercialized by us might otherwise be able to offer to payors.

Potential competitors also include academic institutions, government agencies and other public and private organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. Many of these competitors are attempting to develop therapeutics for our target indications.

Currently in the United States, there are relatively few medications approved for the prevention of episodic and chronic migraines, and no approved drug procedure for prevention for disabling episodic migraine (by which we mean a healthcare provider-administered drug product falling under medical benefit reimbursement, as opposed to pharmacy benefit reimbursement). Most of the medications used today are generics that are prescribed for abortive treatment of migraines. Medications commonly used for

prevention of episodic and chronic migraine include beta blockers such as propranolol, marketed by Wyeth, and other treatments such as topiramate, marketed by Johnson & Johnson, and sodium valproate, marketed by Divalproex. In addition, Botox, marketed by Allergan, is approved for the prevention of chronic migraine and commonly prescribed for disabling episodic migraine. There are also several other companies, Amgen Inc., Eli Lilly and Company, or Eli Lilly, and Teva Pharmaceuticals Industries Limited, or Teva, that are developing calcitonin gene-related peptide, or CGRP, blocking therapies using monoclonal antibodies similar to eptinezumab designed for subcutaneous administration by patients for migraine prevention. Other companies may be in later stages of development than we are or may progress their product candidates through clinical trials faster than our product candidates and, therefore, may obtain FDA or other regulatory approval for their products before we obtain approval for ours. Amgen's anti-CGRP therapy, Aimovig, which they have partnered with Novartis, was approved by the FDA and commercially launched in the United States in May 2018. Aimovig was approved by the European Commission in July 2018. We are aware that Eli Lilly and Teva have also announced that they have made BLA submissions for their competing anti-CGRP therapies, which, if approved, would enable them to commercialize their therapies before we are able to do so with eptinezumab.

Many of our competitors, including a number of large pharmaceutical companies that compete directly with us, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Our competitors may develop products that are more effective, safer, more convenient to administer or less costly than any that we are developing or that would render our product candidates obsolete or non-competitive. It is possible that our competitors might receive FDA or other regulatory approval for their products before us. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient enrollment for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Delays in the enrollment of patients in our clinical trials could increase our development costs and delay completion of the trials and delays in enrollment of patients in any of our future collaborators' clinical trials could delay completion of any of our future collaborators' trials.

We may not be able to initiate or continue clinical trials for eptinezumab or any of our other product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or other regulatory authorities. Even if we are able to enroll a sufficient number of patients in our clinical trials, if the pace of enrollment is slower than we expect, the development costs for our product candidates may increase and the completion of our trials may be delayed or our trials could become too expensive to complete.

We can provide no assurance that we will be able to enroll patients in any ongoing or planned clinical trial at a sufficient pace to complete the clinical trials within our projected time frame. Completing ongoing and future migraine trials will require us to continue to activate new clinical trial sites and to enroll patients at forecasted rates at both new and existing clinical trial sites. Our forecasts regarding the rates of clinical site activation and patient enrollment at those sites are based on a number of assumptions, including assumptions based on experience with prior eptinezumab clinical trials. However, there can be no assurance that those forecasts will be accurate or that we will complete our ongoing and planned eptinezumab trials on schedule. During the initial months of our clinical trials, the number of clinical sites activated and the number of patients enrolled at each clinical site per month could be lower than we have forecasted and, as a result, we might need to make a number of adjustments to the clinical trial plan,

including increasing the number of clinical trial sites. We can provide no assurance that those adjustments will be sufficient to enable us to complete the trials within our anticipated time frame. In addition, we may determine it necessary to increase the target number of patients to be enrolled in a clinical trial, which could extend the time necessary to complete such clinical trial. If we experience delays in enrollment, our ability to complete the trials could be materially adversely affected.

If serious adverse events, or SAEs, are identified during the development of eptinezumab or any of our product candidates, we or any of our future collaborators may need to abandon development of that product candidate.

Our most advanced product candidate, eptinezumab, is still in clinical development and its risk of failure is high. It is impossible to predict when or if eptinezumab or any of our existing or future product candidates will prove effective and safe enough to receive regulatory approval.

Various SAEs have been observed across all clinical trials to date for eptinezumab. The relevant clinical investigators concluded that all observed SAEs to date were found to be unrelated to eptinezumab. We have observed some injection-site reactions, or ISRs, in Phase 1 clinical trials of subcutaneous and intramuscular injections of eptinezumab. Additional studies or requirements from the FDA for future studies may be necessary to address these ISRs.

There can be no assurance that our ongoing or planned trials for eptinezumab will not fail due to safety issues. In such an event, we might need to abandon development of eptinezumab.

We rely on third parties to conduct and support our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.

We do not independently conduct clinical trials for our product candidates. We rely on third parties, such as contract research organizations, or CROs, clinical data management organizations, medical institutions and clinical investigators, to perform this function. Our reliance on these third parties for clinical development activities reduces our control over these activities but does not relieve us of our responsibilities. Furthermore, some of the sites for our clinical trials are outside the United States. The performance of these sites may be adversely affected by various issues, including less advanced medical infrastructure, lack of familiarity with conducting clinical trials in accordance with U.S. standards, insufficient training of personnel, communication difficulties or change in local regulations. We remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the study. Moreover, the FDA requires us to comply with standards, commonly referred to as Good Clinical Practices, or GCP, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of patients in clinical trials are protected. Furthermore, these third parties may also have relationships with other entities, including our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, regulatory approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our products.

We also rely on other third parties to store and distribute supplies for our clinical trials. Any performance failure on the part of our existing or future distributors could delay clinical development or regulatory approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential product revenues.

The manufacture of our product candidates is complex and we may encounter difficulties in production. If we or any of our third-party contract manufacturing organizations, or CMOs, encounter such difficulties, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped.

The process of manufacturing our products is complex, highly-regulated and subject to multiple risks. The manufacture of biologics involves complex processes, including developing cells or cell systems to produce the biologic, growing large quantities of such cells and harvesting and purifying the biologic produced by them. As a result, the cost to manufacture biologics is generally far higher than traditional small molecule chemical compounds, and the biologics manufacturing process is less reliable and is difficult to reproduce. Manufacturing biologics, such as eptinezumab and other product candidates, is highly susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We utilize third-party CMOs to produce eptinezumab using our proprietary yeast production technology.

The manufacturing facilities in which our product candidates are made could be adversely affected by equipment failures, labor shortages, natural disasters, power failures and numerous other factors. There are risks associated with

scaling-up manufacturing to commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, lot consistency and timely availability of raw materials. Even if we or any of our future collaborators obtain regulatory approval for any of our product candidates, there is no assurance that manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. If our or any of our future collaborators' manufacturers are unable to produce sufficient quantities of an approved product for commercialization, commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

We historically relied on a single smaller scale CMO to manufacture and provide us with clinical supplies of eptinezumab. We have entered into agreements with other CMOs to manufacture eptinezumab drug substance and drug product at larger scale as we prepare for commercialization. We are conducting a pharmacokinetic comparability study of our initial commercial supply of eptinezumab for our BLA submission planned for the first quarter of 2019. We expect to use eptinezumab manufactured by our commercial suppliers in future clinical studies. We anticipate there will be continued interaction with additional CMOs as we advance other product candidates. Scaling up a biologic manufacturing process is a difficult and uncertain task, and we may not be successful in transferring our production system or a manufacturer may not have the necessary capabilities to complete the implementation and development process. If we are unable to adequately validate or scale-up the manufacturing process for eptinezumab with a manufacturer, we will need to transfer to another manufacturer and complete the manufacturing validation process, which can be

lengthy. If we are able to adequately validate and scale-up the manufacturing process for eptinezumab or other product candidates with a manufacturer, we will still need to negotiate with such manufacturer an agreement for commercial supply and it is not certain we will be able to come to agreement on terms acceptable to us.

Our yeast-based production system used for the manufacture of eptinezumab is a non-traditional antibody production platform and as we or any of our future collaborators produce product in commercial quantities, we or any such collaborators may experience unforeseen safety or other manufacturing issues which would adversely affect the commercialization of eptinezumab or any of our future product candidates.

We rely on third-party CMOs to manufacture and supply eptinezumab. If one of our suppliers or manufacturers fails to perform adequately or fulfill our needs, we may be required to incur significant costs and devote significant efforts to find new suppliers or manufacturers and may also face delays in the development and commercialization of our product candidates.

We currently do not own manufacturing facilities for clinical-scale manufacturing of our product candidates and we rely upon third-party CMOs to manufacture and supply drug product for our clinical trials. The manufacture of pharmaceutical products in compliance with the FDA's current good manufacturing practices, or cGMP, requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, including difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced cGMP requirements, other federal and state regulatory requirements and foreign regulations. If our manufacturers were to encounter any of these difficulties or otherwise fail to comply with their obligations to us or under applicable regulations, our ability to provide study drugs in our clinical trials would be jeopardized. Any delay or interruption in the supply of clinical trial materials could delay the completion of our clinical trials, increase the costs associated with maintaining our clinical trial programs and, depending upon the period of delay, require us to commence new trials at significant additional expense or terminate the trials completely.

All manufacturers of our product candidates must comply with cGMP requirements enforced by the FDA through its facilities inspection program. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. Manufacturers of our product candidates may be unable to comply with these cGMP requirements and with other FDA, state and foreign regulatory requirements. The FDA or similar foreign regulatory agencies may also implement new standards at any time, or change their interpretation and enforcement of existing standards for manufacture, packaging or testing of products. We have little control over our manufacturers' compliance with these regulations and standards. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall or withdrawal of product approval. If the safety of any product supplied is compromised due to our manufacturers' failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize our products and we may be held liable for any injuries sustained as a result. Any of these factors could cause a delay of clinical trials, regulatory submissions, approvals or commercialization of our product candidates, entail higher costs or impair our reputation.

We historically relied on a single smaller scale CMO to manufacture and provide us with clinical supplies of eptinezumab. We have entered into agreements with other CMOs to manufacture eptinezumab drug substance and drug product at larger scale as we prepare for commercialization. We anticipate there will be continued interaction with additional CMOs as we advance other product candidates. Our current agreements do not, and our future agreements may not, provide for an entire supply of the drug product necessary for all anticipated clinical trials or for full-scale commercialization. If a CMO terminates its agreement with us or otherwise becomes unable to fulfill its supply obligations, or if we and any future CMO cannot agree to the terms and conditions for provision of the drug

product necessary for our clinical and commercial supply needs, our clinical trials and commercialization efforts could be delayed until a qualified alternative supplier is identified, the manufacturing process is qualified and validated and we have agreed on the terms and conditions for such alternative supplier to supply product for us, which would have an adverse impact on our business and prospects.

Eptinezumab is a biologic and therefore requires complex production processes. Transferring the production process to a new manufacturer would be particularly difficult, time-consuming and expensive and may not yield comparable product. Although alternative sources of supply exist, the number of third-party suppliers with the necessary manufacturing and regulatory expertise and facilities necessary to manufacture eptinezumab and any other product candidates we may develop is limited, and may be expensive and take a significant amount of time to arrange for alternative suppliers. New suppliers of any product candidate would be required to qualify under applicable regulatory requirements. Obtaining the necessary FDA approvals or other qualifications under applicable regulatory requirements could result in a significant interruption of supply and could require the new manufacturer to bear significant additional costs which may be passed on to us. Our CMC activities supporting our planned BLA submission for eptinezumab include a pharmacokinetic comparability study to be completed in the second half of 2018. In the event that eptinezumab from our initial commercial supply performs differently from our clinical supply of eptinezumab in this comparability study, we may be required to

conduct additional studies to understand such differences. The scope of any such additional studies could delay or otherwise have an adverse impact on our BLA and commercialization plans and timing.

Even if eptinezumab or any of our other product candidates receive regulatory approval, they may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

If eptinezumab or any of our other product candidates receive regulatory approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors and others in the medical community. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including the following:

- the efficacy and potential advantages compared to alternative treatments;
- the prevalence and severity of any side-effects;
- the price we or any of our future collaborators charge for our products;
- the availability of third-party coverage and adequate reimbursement;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these new therapies; and
- the size and effectiveness of our sales, marketing and distribution support.

If our product candidates are approved and do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable on a sustained basis.

We currently have no sales or distribution personnel or infrastructure and only limited marketing capabilities. If we are unable to develop a sales, marketing and distribution infrastructure on our own or through collaborations or other marketing arrangements, we will not be successful in commercializing eptinezumab or any of our future products.

We do not currently have sales or distribution capabilities and have no experience as an organization in the sale, marketing and distribution of therapeutic products. To achieve commercial success for any approved product, we must either develop a sales and marketing organization or outsource these functions to third parties. Assuming regulatory approval, we plan to focus our initial commercialization efforts on high-prescribing neurologists and headache centers in the United States employing a specialty sales force that we plan to establish. To maximize the potential commercial opportunity of eptinezumab while we focus on the U.S. specialty market, we may explore strategic arrangements that provide additional capabilities and infrastructure while improving access for physicians and patients.

There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is

expensive and time-consuming and could delay any product launch. If the commercial launch of a product for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we do not have another product to sell in the same specialty market. We also may not be successful entering into arrangements with third parties to sell and market our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively and could damage our reputation. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing eptinezumab or any other product candidates.

If we are able to commercialize eptinezumab or any other product candidates, the products may become subject to unfavorable pricing regulations or third-party reimbursement practices, thereby harming our business.

The regulations that govern pricing and reimbursement for new therapeutic products vary widely from country to country. Some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject

to continuing governmental control even after initial approval is granted. As a result, we or any of our future collaborators might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay commercial launch of the product and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in our products, even if our product candidates obtain regulatory approval.

Our and any of our future collaborators' ability to commercialize any product candidates successfully also will depend in significant part on the extent to which coverage and adequate reimbursement for these products and related treatments becomes available from government health administration authorities, private health insurers and other third-party payors. Third-party payors decide which medications they will cover and establish reimbursement levels. A primary focus in the U.S. healthcare industry and elsewhere is cost containment. Increasingly, third-party payors are requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that coverage will be available for any product that we or any of our future collaborators commercialize and, if coverage is available, what the level of reimbursement will be. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

Reimbursement may impact the demand for, or the price of, any product for which we or any of our future collaborators obtain approval. Obtaining coverage and adequate reimbursement for our products may be particularly difficult because of the higher prices often associated with products administered under the supervision of a physician. If reimbursement is not available or is available only to limited levels, we or any of our future collaborators may not be able to successfully commercialize any product that has been approved.

There may be significant delays in obtaining reimbursement for newly approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or regulatory authorities in other countries. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our or any of our future collaborators' costs, including research, development, manufacture, sale and distribution. Interim payments for new products, if applicable, may also not be sufficient to cover our or any of our future collaborators' costs and may not be made permanent. Payment rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower cost products that are already reimbursed and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the United States. Private third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our or any of our future collaborators' inability to promptly obtain coverage and profitable payment rates from both government funded and private payors for newly developed products could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we or any of our future collaborators may develop;

- injury to our reputation and significant negative media attention;
- withdrawal of patients from clinical trials or cancellation of trials;
- significant costs to defend the related litigation;
- substantial monetary awards;
- loss of revenues; and
- the inability to commercialize any products that we may develop.

We currently have $20 million in product liability insurance coverage for our clinical trials, which may not be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Marketing approval of our product candidates in international markets will subject us to additional costs and a variety of risks associated with international operations.

We intend to pursue marketing approvals for our product candidates in international markets directly or with partners and will be subject to additional costs and additional risks related to international operations, including:

- different regulatory requirements for drug approvals in foreign countries;
- reduced protection for intellectual property 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 labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- the impact of the vote by the United Kingdom decided by referendum to leave the European Union (commonly referred to as “Brexit”); and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

We may expend our limited resources to pursue a particular product candidate or disease and fail to capitalize on product candidates or diseases that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus our research programs and product candidates for a specific disease. As a result, we may forego or delay pursuit of opportunities with other product candidates or

other diseases that may later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific diseases may not yield any commercially viable products.

If we do not accurately evaluate the commercial potential for a particular product candidate in the right disease, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to retain sole development and commercialization rights.

We may not be successful in our efforts to use and enhance our proprietary antibody platform to create a pipeline of product candidates and develop commercially successful products.

We have used our proprietary antibody platform for the selection of monoclonal antibodies to create eptinezumab, ALD1910 and other future product candidates that we are currently evaluating. We are at an early stage of development and our platform has not yet, and may never, lead to approved or commercially successful products. Even if we are successful in continuing to build our

pipeline, the future product candidates that we evaluate may not be suitable for clinical development, including as a result of their harmful side-effects, limited efficacy or other characteristics that make it unlikely such product candidates will receive regulatory approval or achieve commercial success. If we do not successfully develop and commercialize product candidates using our proprietary antibody platform, we may not be able to obtain product or collaboration revenues in future periods, which would harm our business and prospects.

If any future collaborations for the development and commercialization of product candidates are not successful, our business may be harmed.

We may choose to enter into collaboration agreements with third parties with respect to our product candidates, including eptinezumab, for their development and commercialization in the United States or in international markets. We will have limited control over the amount and timing of resources that any of our future collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend in part on any such collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Collaborations involving our product candidates are subject to numerous risks, which may include the following:

- collaborators may have significant discretion in determining the efforts and resources that they will apply to collaborations;

- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;

- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;

- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;

- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;

- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;

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- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources;

- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and

- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

Any termination or disruption of any future collaboration could result in delayed development of product candidates, increased cost to develop product candidates or termination of development of a product candidate.

We may engage in future acquisitions that increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities and subject us to other risks.

We may evaluate various strategic transactions, including licensing or acquiring complementary products, technologies or businesses. Any potential acquisitions may entail numerous risks, including increased operating expenses and cash requirements, assimilation of operations and products, retention of key employees, diversion of our management's attention and uncertainties in our ability to maintain key business relationships of the acquired entities. In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant

future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

Risks Related to Government Regulation

The regulatory approval process is expensive, time consuming and uncertain and may prevent us or our any of our future collaboration partners from obtaining approvals for the commercialization of some or all of our product candidates.

Among other things, the research, testing, manufacturing, labeling, approval, selling, import, export, marketing and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, which regulations differ from country to country. Neither we nor any future collaboration partner is permitted to market our product candidates in the United States until we receive approval of a BLA from the FDA. We have not submitted an application or received marketing approval for any of our product candidates. Obtaining approval of BLA can be a lengthy, expensive and uncertain process. In addition, failure to comply with FDA and other applicable U.S. and foreign regulatory requirements may subject us to administrative or judicially imposed sanctions, including the following:

- warning letters;
- civil or criminal penalties and fines;
- injunctions;
- suspension or withdrawal of regulatory approval;
- suspension of any ongoing clinical trials;
- voluntary or mandatory product recalls and publicity requirements;
- refusal to accept or approve applications for marketing approval of new drugs or biologics or supplements to approved applications filed by us;
- restrictions on operations, including costly new manufacturing requirements; or
- seizure or detention of our products or import bans.

Prior to receiving approval to commercialize any of our product candidates in the United States or abroad, we and any of our future collaboration partners must demonstrate with substantial evidence from well-controlled clinical trials,

and to the satisfaction of the FDA and other regulatory authorities abroad, that such product candidates are safe and effective for their intended uses. Results from preclinical studies and clinical trials can be interpreted in different ways. Even if we and any of our future collaboration partners believe the preclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. Administering any of our product candidates to humans may produce undesirable side-effects, which could interrupt, delay or cause suspension of clinical trials of our product candidates and result in the FDA or other regulatory authorities denying approval of our product candidates for any or all targeted indications.

Regulatory approval of BLA is not guaranteed, and the approval process is expensive and may take several years. The FDA also has substantial discretion in the approval process. Despite the time and expense exerted, failure can occur at any stage, and we could encounter problems that cause us to abandon or repeat clinical trials, or perform additional preclinical studies and clinical trials. The number of preclinical studies and clinical trials that will be required for FDA approval varies depending on the product candidate, the disease or condition that the product candidate is designed to address and the regulations applicable to any particular product candidate.

The FDA can delay, limit or deny approval of a product candidate for many reasons, including, but not limited to, the following:

- a product candidate may not be deemed safe or effective;
- FDA officials may not find the data from preclinical studies and clinical trials sufficient;
- the FDA might not approve our or our third-party manufacturers' processes or facilities; or

- the FDA may change its approval policies or adopt new regulations.

If any of our product candidates fails to demonstrate safety and efficacy in clinical trials or does not gain regulatory approval, our business will be harmed.

Even if we receive regulatory approval for a product 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 any of our future collaboration partners receive for our product 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 trials 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 product 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, among other things, 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. Furthermore, regulatory authorities must 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 product candidates or the manufacturing facilities for our product 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;
- suspension or withdrawal of regulatory approval;
- suspension of any ongoing clinical trials;
- voluntary or mandatory product recalls and publicity requirements;
- refusal to approve pending applications for marketing approval of new drugs or supplements to approved applications filed by us;

- restrictions on operations, including costly new manufacturing requirements; or

- seizure or detention of our products or import bans.

The regulatory requirements and policies may change and additional government regulations may be enacted for 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.

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

We or a future collaboration partner may market eptinezumab and any 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 EMA, 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.

We have had limited interactions with foreign regulatory authorities, and 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 trials 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.

Healthcare reform measures could hinder or prevent our product candidates' commercial success.

In the United States, there have been and we expect there will continue to be a number of legislative and regulatory changes to the healthcare system in ways that could affect our future revenues and profitability and the future revenues and profitability of our potential customers. Federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services, improve quality of care, and expand access to coverage. For example, one of the most significant healthcare reform measures in decades, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively, the ACA, was enacted in 2010. The ACA contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse measures. However, in January 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. In Congress, the U.S. House of Representatives passed ACA replacement legislation known as the American Health Care Act of 2017 in May 2017, which was not introduced in the Senate. More recently, the Senate Republicans have proposed multiple bills to repeal and replace portions of the ACA. Although none of these measures have been enacted, Congress may consider other legislation to repeal or replace certain elements of the ACA. On October 12, 2017, President Trump signed another Executive Order directing certain federal agencies to propose regulations or guidelines to permit small businesses to form association health plans, expand the availability of short-term, limited duration insurance, and expand the use of health reimbursement arrangements, which may circumvent some of the requirements for health insurance mandated by the ACA. We cannot know how efforts to repeal and replace the ACA or any future healthcare reform legislation will impact our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, which triggered the legislation's automatic reduction to several government programs, including aggregate reductions to Medicare payments to providers of up to 2% per fiscal year that went into effect on April 1, 2013, following passage of the Bipartisan Budget Act of 2015, and will remain in effect through 2025 unless additional Congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which, among other things, further reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

There have been and likely will continue to be legislative and regulatory proposals at the federal and state levels directed at containing or lowering the cost of health care. For example, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. We cannot predict the initiatives that may be adopted in the future or their full impact. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of health care may adversely affect:

- our ability to set a price we believe is fair for our products;
- our ability to generate revenues and achieve or maintain profitability; and
- the availability of capital for our business.

Furthermore, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to Institutional Review Boards for reexamination, which may impact the costs, timing or successful completion of a clinical trial. Data from clinical trials may receive greater scrutiny with respect to safety, which may make the FDA or other regulatory authorities more likely to terminate or suspend clinical trials before completion, or require longer or additional clinical trials that may result in substantial additional expense and a delay or failure in obtaining approval or approval for a more limited indication than originally sought.

Given the serious public health risks of high profile adverse safety events with certain drug products, the FDA may require, as a condition of approval, costly risk evaluation and mitigation strategies, which may include safety surveillance, restricted distribution and use, patient education, enhanced labeling, special packaging or labeling, expedited reporting of certain adverse events, preapproval of promotional materials and restrictions on direct-to-consumer advertising.

If we fail to comply with healthcare laws, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws and regulations, including those pertaining to fraud and abuse and patients' rights, are and will be applicable to our business. We could be subject to healthcare regulation by both the federal government and the states in which we conduct our business. The healthcare laws and regulations that may affect our ability to operate include, without limitation:

- the federal Anti-Kickback Statute, which prohibits, among other things, any person or entity from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs;

- federal false claims laws, including the federal civil False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment that are false or fraudulent, or knowingly making false statements to avoid, decrease, or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- the federal Physician Payments Sunshine Act under the ACA, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program to annually report to the U.S. Department of Health and Human Services' Centers for Medicare & Medicaid Services, or CMS, information related to payments and other transfers of value provided to physicians and teaching hospitals and physician ownership and investment interests;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, which imposes requirements on certain types of entities and individuals regarding the conduct of certain electronic healthcare transactions and the security and privacy of protected health information; and

- state 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; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state laws that require drug manufacturers to report information related to payments and other transfers of value to other healthcare providers and healthcare entities, or marketing expenditures; and state and foreign laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

The ACA, among other things, amends the intent requirement of the federal Anti-Kickback Statute and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to commit a violation. In addition, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

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 administrative, civil and criminal penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in federal healthcare programs, integrity obligations, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations, which could adversely affect our ability to operate our business and our financial results. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

Our failure to comply with data protection laws and regulations could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results.

EU Member States, Switzerland and other countries have adopted data protection laws and regulations, which impose significant compliance obligations. For example, European Union, or EU, member states and other foreign jurisdictions, including Switzerland, have adopted data protection laws and regulations which impose significant compliance obligations. Moreover, the collection and use of personal health data in the EU is governed by the EU General Data Protection Regulation, or the GDPR, which became effective in May 2018. The GDPR, which is wide-ranging in scope, imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification and the use of third party processors in connection with the processing of personal data. The GDPR also imposes strict rules on the transfer of personal data out of the EU to the U.S., provides an enforcement authority and imposes large penalties for noncompliance, including the potential for fines of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. The GDPR requirements apply not only to third-party transactions, but also to transfers of information between us and our subsidiaries, including employee information. The GDPR increases our responsibility and liability in relation to personal data that we process, including in clinical trials, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, which could divert management's attention and increase our cost of doing business. In addition, new regulation or legislative actions regarding data privacy and security (together with applicable industry standards) may increase our costs of doing business. In this regard, we expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data protection in the United States, the EU and other jurisdictions, and we cannot determine the impact such future laws, regulations and standards may have on our business.

Risks Related to Intellectual Property

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.

We are a party to intellectual property license agreements with third parties. For example, we have a non-exclusive, royalty bearing license with Teva Pharmaceuticals International GmbH, or Teva GmbH, for its CGRP patent portfolio to develop, manufacture and commercialize eptinezumab in the United States and worldwide, excluding Japan and Korea. We also have a third-party royalty free license associated with the Keck Graduate Institute for our yeast-based proprietary manufacturing technology. We may enter into additional license agreements in the future. Our existing license agreements impose, and we expect that our future license agreements will impose, various diligence, royalty payment, milestone payment, insurance and other obligations on us. If we fail to comply with these obligations or our other obligations in our license agreements, our licensors may have the right to terminate these agreements, in which event we may not be able to develop and market any product or use any platform technology that is covered by these agreements. 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 or our not having sufficient intellectual property rights to operate our business. The occurrence of such events could materially harm our business.

Our ability to successfully commercialize our products may be impaired if we are unable to obtain and maintain effective intellectual property rights for our proprietary antibody platform and product candidates.

Our success depends in large part on our and our licensors' ability to obtain and maintain patent and other intellectual property protection in the United States and in other countries with respect to our proprietary antibody platform and products. In some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents or enforce the patents, covering technology or products that we license from third parties. Therefore, we cannot be certain that these patents and applications will be prosecuted and enforced in a manner consistent with the best interests of our business. In addition, if third parties who license patents to us fail to maintain such patents, or lose rights to those patents, the rights we have licensed may be reduced or eliminated. Because certain intellectual property rights are shared between us and any of our future collaborators, it is possible that disputes may arise related to the distribution of those rights.

We have sought to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and products 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. The standards that the United States Patent and Trademark Office, or USPTO, uses to grant patents are not always applied predictably or uniformly and can change. Consequently, we cannot be certain as to whether pending patent applications will be allowed; and if allowed, we cannot be certain as to the type and extent of patent claims that will be issued to us in the future. 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 products and technologies.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain and involves complex legal and factual questions for which legal principles remain unresolved. In recent years, patent rights have been the subject of significant litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our licensors' patent rights are highly uncertain. Our and our licensors' pending and future patent applications may not result in patents being issued which protect our technology or products or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned and licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions.

In March 2013, the United States converted to a first-to-file patent system under the recently enacted America Invents Act. With this change, the United States patent system was brought into closer conformity with the patent systems of other countries, the vast majority of which operate as first-to-file patent systems. Under the former system, and assuming the other requirements for patentability were met, the first to invent was entitled to the patent. A number of our patents and patent applications are subject to the first-to-invent system because they originated prior to the March 2013 cutoff. Under the new United States system, and outside the United States, the first to file a patent application is entitled to the patent, with certain exceptions. A number of our patents and patent applications are subject to the new first-to-file system in the United States because they originated after the March 2013 cutoff. The full effect of these changes remains unclear as the USPTO endeavors to implement various regulations concerning the new system. Furthermore, the courts have yet to address the vast majority of these provisions and the applicability of the America Invents Act and new regulations on specific patents discussed herein have not been determined and would need to be

reviewed. We may become involved in opposition, interference, post-grant or derivation proceedings challenging our patent rights or the patent rights of others, and the outcome of any proceedings are highly uncertain. An adverse determination in any such proceeding could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Even if our owned and licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of future product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours or otherwise provide us with a competitive advantage.

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. The standards that courts use to interpret patents are not always applied predictably or uniformly and can change, particularly as new technologies develop. As a result, we cannot predict with certainty how much protection, if any, will be given to our patents if we attempt to enforce them and they are challenged in court. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Inequitable conduct is frequently raised as a defense during intellectual property litigation. It is believed that all parties involved in the prosecution of our patent applications have complied with their duties of disclosure in the course of prosecuting our patent applications, however, it is possible that legal claims to the contrary could be asserted if we were engaged in intellectual property litigation, and the results of any such legal claims are uncertain due to the inherent uncertainty of litigation. If a court determines that any party involved in the prosecution of our patents failed to comply with their duty of disclosure, the subject patent would be unenforceable. 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 harm our business.

Third parties may assert infringement claims against us, or other parties we have agreed to indemnify, based on existing patents or patents that may be granted in the future. Furthermore, since patent applications are published some time after filing, and because applications can take several years to issue, there may be pending third-party patent applications that are unknown to us, which may later result in issued patents.

We may initiate litigation or other legal proceedings with respect to patents held by others. Because of the inevitable uncertainty in intellectual property legal proceedings, any such proceedings, if initiated, may not ultimately be resolved in our favor regardless of our perception of the merits. If we lose such a proceeding, or are found to infringe a third party’s intellectual property rights in any jurisdiction, we may not be to engage in commercialization and related activities for a product candidate for its intended use in such jurisdiction without obtaining a license from such third party. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we are able to obtain a license, it may 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 commercializing the infringing technology or product. In addition, in any such proceeding or litigation, we could be found liable for monetary damages, including in the United States treble damages if we are found to have willfully infringed a patent, and attorneys’ fees. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations.

In July 2014, we and Eli Lilly each filed an opposition to a European patent owned by Teva GmbH with claims directed to CGRP antagonist antibodies and use of such CGRP antagonist antibodies in human therapy for the prevention or treatment of headache such as migraine. In January 2018, we entered into a European patent settlement and global license agreement with Teva GmbH pursuant to which we received a non-exclusive license to Teva GmbH’s CGRP patent portfolio, which includes the opposed European patent, to develop, manufacture and commercialize eptinezumab in the United States and worldwide, excluding Japan and Korea, and agreed to withdraw

our opposition.

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

In addition to our patented technology and products, 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, collaborators and consultants. We also have agreements with our employees and selected consultants 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. Furthermore, our trade secrets could be disclosed, misappropriated or otherwise become known or be independently discovered by our competitors. Our trade secrets can be lost through their inadvertent or advertent disclosure to others. 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 harm our business.

We may be subject to claims that our employees have wrongfully used or disclosed intellectual property of their former employers. Intellectual property litigation or proceedings could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees 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 these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. 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 or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property related proceedings could impair our ability to compete in the marketplace.

Risks Related to Our Operations and Personnel

Our future success depends on our ability to retain our executive officers and other key employees and to attract, retain and motivate qualified personnel.

We are highly dependent on our executive officers and other key employees. The employment of our executive officers and other key employees is typically at-will and our executive officers and other key employees may terminate their employment with us at any time. The loss of the services of any of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives.

Recruiting and retaining other qualified scientific, clinical, manufacturing and sales and marketing personnel is critical to our success. We may not be able to attract and retain critical personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by third parties and have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

We expect to expand our development, regulatory affairs, sales and marketing and other capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

Over the next several years, if any of our product candidates receive marketing approval, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, regulatory affairs, sales and marketing and other functional areas, including finance, accounting and legal. For example, if eptinezumab is approved, we plan to build a specialty sales force targeting high-prescribing neurologists and headache centers in the United States. To manage our anticipated future growth, we must 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.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we

could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous materials.

In addition, we may be required to incur substantial costs to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may divert resources away from our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Business disruptions could harm our future revenues and financial condition and increase our costs and expenses.

Our operations could be subject to earthquakes, power shortages, telecommunications failures, floods, hurricanes, fires, extreme weather conditions, medical epidemics and other natural or manmade disasters or business interruptions. The occurrence of any of these business disruptions could harm our operations and financial condition and increase our costs and expenses. Our corporate headquarters is located in Washington and certain clinical sites for our product candidates, operations of our existing and future partners and suppliers are or will be located in Washington near major earthquake faults. The ultimate impact on us, our significant partners, suppliers and our general infrastructure of being located near major earthquake faults and being consolidated in certain geographical areas is unknown, but our operations and financial condition could suffer in the event of a major earthquake or other natural or manmade disaster.

Our internal computer systems, or those of our CROs 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 and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such system failure, accident or security breach to date, 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. For example, the loss of clinical trial data from completed or ongoing clinical trials for any of our product 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 of our product candidates could be delayed.

Risks Related to Ownership of Our Securities

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance.

Our quarterly and annual operating results have fluctuated in the past and may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. From time to time, we may enter into collaboration agreements with other companies that include development funding and significant upfront and milestone payments, and amounts earned from collaboration agreements may be an important source of our revenues. Accordingly, our revenues, if any, will depend on development funding and the achievement of development and

clinical milestones under any of our future collaboration arrangements, as well as any potential future license agreements and sales of our products, if approved. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in our operating results from one period to the next.

Our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and cost of, and level of investment in, research and development activities relating to our product candidates, which may change from time to time;

- the cost of manufacturing our product candidates, which may vary depending on the quantity of production and the terms of our agreements with manufacturers;

- expenditures that we will or may incur to acquire or develop additional product candidates and technologies;

- the level of demand for our product candidates, should they receive approval, which may vary significantly;

- future accounting pronouncements or changes in our accounting policies;

- the timing and success or failure of clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners; and

- the risk/benefit profile, cost and reimbursement policies with respect to our products candidates, if approved, and existing and potential future drugs that compete with our product candidates.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated operating results guidance we may provide.

Our stock price may be volatile, and purchasers of our common stock could incur substantial losses. Volatility in the market price and trading volume of our common stock could adversely impact the trading price of the Convertible Notes.

Our stock price has fluctuated in the past and is likely to be volatile in the future. Since January 1, 2015, the reported sale price of our common stock has fluctuated between $8.60 and $54.90 per share. For example, on June 26, 2017, prior to our announcement of our PROMISE 1 data, the closing price of our common stock was $18.70 per share. Following the announcement of our PROMISE 1 data, the closing price of our common stock on June 27, 2017 was $13.48, and since that date the reported sale price of our common stock has been as low as $8.60 per share.

The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may experience losses on their investment in our common stock. The market price for our common stock may be influenced by many factors, including the following:

- the success of competitive products or technologies;

- results of clinical trials of our product candidates or those of our competitors;

- regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to our product candidates;

- introductions and announcements of future product candidates by us, any of our future collaborators, or our competitors, and the timing of these introductions or announcements;

- actions taken by regulatory agencies with respect to our or our competitors' product candidates, clinical trials, manufacturing process or sales and marketing terms;

- variations in our financial results or those of companies that are perceived to be similar to us;

- the success of our efforts to discover, acquire or in-license additional products or product candidates;

- developments concerning our future collaborations, including but not limited to those with our sources of manufacturing supply and our future collaborators;

- manufacturing disruptions;

- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;

- developments or disputes concerning patents or other proprietary rights, including litigation matters and our ability to obtain patent protection for our product candidates;

- our ability or inability to raise additional capital and the terms on which we raise it;

- the recruitment or departure of key personnel;

- changes in the structure of healthcare payment systems;

- market conditions in the pharmaceutical and biotechnology sectors;

- actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally;

- trading volume of our common stock;

- sales of our common stock by us or our stockholders;

- changes in our board of directors or key personnel;

- the expiration of contractual lock-up agreements;

- changes in our capital structure, such as future issuances of debt or equity securities;

- short sales, hedging and other derivative transactions involving our capital stock;

- general economic, industry and market conditions in the United States and abroad, including, for example, the impact of Brexit or similar events on global financial markets;

- other events or factors, including those resulting from war, incidents of terrorism or responses to these events; and

- the other risks described in this “Risk Factors” section.

These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. In the past, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and

diversion of management's attention and resources, which could harm our business.

A decrease in the market price of our common stock would likely adversely impact the trading price of the Convertible Notes. The market price of our common stock could also be affected by possible sales of our common stock by investors who view the Convertible Notes as a more attractive means of equity participation in us and by hedging or arbitrage trading activity that we expect to develop involving our common stock. This trading activity could, in turn, affect the trading price of the Convertible Notes.

Substantial future sales of shares of our common stock could cause the market price of our common stock and the trading price of the Convertible Notes to decline. This could cause the market price of our common stock and trading price of the Convertible Notes to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock into the public market could occur at any time. We may issue shares of our common stock or equity securities senior to our common stock in the future for a number of reasons, including to finance our operations and business strategy, to adjust our ratio of debt-to-equity, to satisfy our obligations upon the exercise of options, or for other reasons. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock, could impair our ability to raise capital through the sale of additional equity securities and could adversely affect the trading price of the Convertible Notes. We are unable to predict the effect that such sales may have on the prevailing market price of our common stock or trading price of the Convertible Notes.

A substantial number of shares of our common stock is reserved for issuance upon conversion of shares of our convertible preferred stock and the Convertible Notes. In addition, as of June 30, 2018, we had options and restricted stock awards outstanding that, if fully exercised or vested, as applicable, would result in the issuance of 10,886,744 shares of common stock. As of June 30, 2018, there were also 1,454,244 shares of common stock reserved for issuance under our 2014 Equity Incentive Plan and 1,785,721

shares of common stock reserved for issuance under our 2014 Employee Stock Purchase Plan. The authorized number of shares under both such benefit plans are subject to automatic annual increases in the number of shares of common stock reserved for future issuance on January 1 of each year through 2024. As of June 30, 2018, there were 1,850,000 shares of common stock reserved for issuance under our 2018 Inducement Award Plan. All of the shares of common stock issuable pursuant to our equity compensation plans have been or will be registered for public resale under the Securities Act of 1933, as amended, or the Securities Act. Accordingly, these shares will be able to be freely sold in the public market upon issuance as permitted by any applicable vesting requirements and the restrictions of Rule 144 under the Securities Act in the case of our affiliates.

The existence of the Convertible Notes may encourage short selling by market participants because the conversion of the Convertible Notes could be used to satisfy short positions, or anticipated conversion of the Convertible Notes into shares of our common stock could depress the price of our common stock.

Moreover, as of June 30, 2018, holders of an aggregate of up to approximately 3.7 million of our common stock have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders.

In addition, in connection with our January 2018 issuance of convertible preferred stock to certain institutional and other accredited investors affiliated with or managed by Redmile Group, LLC, collectively, Redmile, we entered into a registration rights agreement with Redmile. Under the registration rights agreement, we filed a prospectus supplement under our current registration statement on Form S-3 (SEC File No. 333-216199), and are required to file, if needed, one or more additional registration statements, as permissible and necessary, for the resale of the shares of our common stock issued or issuable upon conversion of the convertible preferred stock and a warrant to purchase an aggregate of 75,000 shares of convertible preferred stock that we may be required to issue to Redmile.

If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, our stock price and trading volume could decline.

The trading market for our common stock depends, in part, on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. If one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. In addition, if our operating results fail to meet the forecast of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

Complying with the laws and regulations affecting public companies has increased and will increase our costs and the demands on management and could harm our operating results.

As a public company, we are incurring significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and rules subsequently implemented by the SEC and Nasdaq impose numerous requirements on public companies, including requiring changes in corporate governance practices. Also, the Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results. Our management and other personnel need to devote a substantial amount of time to compliance with these laws and regulations. These burdens may increase as new legislation is passed and implemented, including any new requirements that the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 may impose on public companies. These requirements have increased and will continue to increase our legal, accounting, and financial compliance costs and have made and will continue to make some activities more time consuming and costly. We expect these rules and regulations may make it difficult and expensive for us to obtain director and officer liability insurance, and in the future, we may be required to

accept reduced policy limits and coverage or to incur substantial costs to maintain the same or similar coverage. These rules and regulations could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or our board committees or as executive officers.

The Sarbanes-Oxley Act requires, among other things, that we assess the effectiveness of our internal control over financial reporting annually and the effectiveness of our disclosure controls and procedures quarterly. Section 404 of the Sarbanes-Oxley Act, or Section 404, requires us to perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on, and our independent registered public accounting firm potentially to attest to, the effectiveness of our internal control over financial reporting. Our compliance with applicable provisions of Section 404 subjects us to substantial accounting expense and to expend significant management time on compliance-related issues. If we are not able to comply with the requirements of Section 404 applicable to us in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

Furthermore, investor perceptions of our company may suffer if deficiencies are found, and this could cause a decline in the market price of our stock. Irrespective of compliance with Section 404, any failure of our internal control over financial reporting could have a material adverse effect on our stated operating results and harm our reputation. If we are unable to implement these requirements effectively or efficiently, it could harm our operations, financial reporting, or financial results and could result in an adverse opinion on our internal control over financial reporting from our independent registered public accounting firm.

Provisions in our corporate charter documents could make an acquisition of us more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our corporate charter and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. Among others, these provisions include the following:

- our board of directors is divided into three classes with staggered three-year terms which may delay or prevent a change of our management or a change in control;

- our board of directors has the right to elect directors to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;

- our stockholders may not act by written consent or call special stockholders' meetings; as a result, a holder, or holders, controlling a majority of our capital stock would not be able to take certain actions other than at annual stockholders' meetings or special stockholders' meetings called by the board of directors, the chairman of the board or the chief executive officer;

- our certificate of incorporation does not provide for cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;

- stockholders must provide advance notice and additional disclosures in order to nominate individuals for election to the board of directors or to propose matters that can be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of our company; and

- our board of directors may issue, without stockholder approval, shares of undesignated preferred stock; the ability to issue undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or

other rights or preferences that could impede the success of any attempt to acquire us.

The fundamental change repurchase feature of the Convertible Notes may delay or prevent an otherwise beneficial attempt to take over our company.

The terms of the Convertible Notes require us to repurchase the Convertible Notes in the event of a fundamental change. A takeover of our company would trigger an option of the holders of the Convertible Notes to require us to repurchase the Convertible Notes. This may have the effect of delaying or preventing a takeover of our company that would otherwise be beneficial to our investors.

Provisions under Delaware law and Washington law could make an acquisition of our company more difficult, limit attempts by our stockholders to replace or remove our current management and limit the market price of our common stock.

In addition to provisions in our corporate charter and our bylaws, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any holder of at least 15% of our capital stock for a period of three years following the date on which the stockholder became a 15% stockholder. Likewise, because our principal executive offices are located in Washington, the anti-takeover provisions of the Washington Business Corporation Act may apply to us under certain circumstances now or in the future. These provisions prohibit a “target corporation” from engaging in any of a broad range of business combinations with any stockholder constituting an “acquiring person” for a period of five years following the date on which the stockholder became an “acquiring person.”

Item 6. Exhibits

Exhibit		Incorporated by Reference				
Number	Description	Form	File No.	Exhibit	Filing Date	Filed Herewith
3.1	Amended and Restated Certificate of Incorporation of Alder BioPharmaceuticals, Inc.	8-K	001-36431	3.1	May 13, 2014	
3.2	Amended and Restated Bylaws of Alder BioPharmaceuticals, Inc.	S-1	333-194672	3.5	April 25, 2014	
3.3	Certificate of Designation of Preferences, Rights and Limitations of Class A-1 Convertible Preferred Stock of Alder BioPharmaceuticals, dated January 12, 2018.	8-K	001-36431	3.1	January 19, 2018	
4.1	Amended and Restated Investors' Rights Agreement, dated as of April 16, 2012, by and among Alder BioPharmaceuticals, Inc. and certain of its stockholders.	S-1	333-194672	4.1	March 19, 2014	
4.2	Amendment No. 1 to Amended and Restated Investors' Rights Agreement, dated as of April 7, 2014, by and among Alder BioPharmaceuticals, Inc. and certain of its stockholders.	S-1	333-194672	4.2	April 25, 2014	
4.3	Form of Common Stock Certificate.	S-1	333-201201	4.3	December 22, 2014	
4.4	Registration Rights Agreement by and between Alder BioPharmaceuticals, Inc. and the buyers listed on the Schedule of Buyers thereto, dated January 12, 2018.	8-K	001-36431	4.1	January 19, 2018	
4.5	Base Indenture, dated February 1, 2018, between the Company and U.S. Bank National Association, as Trustee.	8-K	001-36431	4.1	February 1, 2018	
4.6	First Supplemental Indenture, dated February 1, 2018, between the Company and U.S. Bank National Association, as Trustee (including the form of 2.50% convertible senior notes due 2025).	8-K	001-36431	4.2	February 1, 2018	
10.1+	Offer Letter between the Company and Robert W. Azelby dated June 4, 2018.					X
10.2+	Form of Amendment to Stock Option Grant Notice and Option Agreement for the 2014 Equity Incentive Plan.					X
10.3+	Form of Stock Option Grant Notice and Option Agreement for the 2014 Equity Incentive Plan (For awards after June 14, 2018).					X
10.4+	Form of Restricted Stock Unit Award Grant Notice and Option Agreement (Time-Based Vesting) for the 2014 Equity Incentive Plan.					X
10.5+	Form of Restricted Stock Unit Award Grant Notice and Option Agreement (Performance-Based Vesting) for the 2014 Equity Incentive Plan.					X
10.6+	2018 Inducement Award Plan.					X
10.7+	Form of Stock Option Grant Notice and Option Agreement (Time-Based Vesting) for the 2018					X

	Inducement Award Plan.	
10.8+	Form of Stock Option Grant Notice and Option Agreement (Performance-Based Vesting) for the 2018 Inducement Award Plan.	X
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a).	X
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a).	X
32.1*	Certifications of Principal Executive Officer and Principal Financial Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X

Exhibit		Incorporated by Reference				
Number	Description	Form	File No.	Exhibit	Filing Date	Filed Herewith
101.INS**	XBRL Instance Document.					X
101.SCH**	XBRL Taxonomy Extension Schema Document.					X
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document.					X
101.DEF**	XBRL Taxonomy Extension Definition Linkbase Document.					X
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document.					X
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document.					X

* The Certifications attached as Exhibits 32.1 that accompany this Quarterly Report on Form 10-Q are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Form 10-Q, irrespective of any general incorporation language contained in such filing.

** Attached as Exhibit 101 to this Quarterly Report on Form 10-Q for the quarter ended June 30, 2018 formatted in XBRL (Extensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Operations, (iii) Condensed Consolidated Statements of Comprehensive Income (Loss), (iv) Condensed Consolidated Statements of Cash Flows, and (v) Notes to Condensed Consolidated Financial Statements, tagged as blocks of text and including detailed tags.

+ Indicates a management contract or compensatory plan.

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.

Alder BioPharmaceuticals, Inc.

Date: August 7, 2018 By: /s/ Robert W. Azelby
Robert W. Azelby
President and Chief Executive Officer
(Principal Executive Officer)

Alder BioPharmaceuticals, Inc.

Date: August 7, 2018 By: /s/ Larry K. Benedict
Larry K. Benedict
Executive Vice President and Principal Accounting Officer
(Principal Financial and Accounting Officer)