ALDER BIOPHARMACEUTICALS INC
Form 10-Q
August 08, 2017

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, 2017

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 4, 2017 the registrant had 67,713,633 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, 2017

INDEX

		Page
PART I. FINANCIAL INFORMATION (Unaudited)		
Item 1.	Condensed Consolidated Financial Statements	3
	Condensed Consolidated Balance Sheets	3
	Condensed Consolidated Statements of Operations	4
	Condensed Consolidated Statements of Comprehensive Loss	5
	Condensed Consolidated Statements of Cash Flows	6
	Notes to Condensed Consolidated Financial Statements	7
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	14
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	23
Item 4.	Controls and Procedures	24
PART II. OTHER INFORMATION		
Item 1.	Legal Proceedings	25
		25

Item 1A. Risk Factors

Item 6. Exhibits 50

SIGNATURES 51

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 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, 2017	December 31, 2016
	(in thousands, except share and per share data)	
Assets		
Current assets		
Cash and cash equivalents	$127,789	$116,216
Short-term investments	96,692	235,651
Prepaid expenses and other assets	21,221	40,380
Inventory	936	936
Total current assets	246,638	393,183
Property and equipment, net	6,714	7,076
Investment in unconsolidated entity	586	865
Other assets	30	8,030
Total assets	$253,968	$409,154
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$19,796	$10,361
Accrued liabilities	14,236	15,437
Deferred rent	92	92
Total current liabilities	34,124	25,890
Long-term deferred rent	423	481
Total liabilities	34,547	26,371
Commitments and contingencies		
Stockholders' equity		
Common stock; $0.0001 par value; 200,000,000 shares authorized; 50,461,985 and 50,368,206 shares issued and outstanding, respectively	5	5
Additional paid-in capital	773,071	761,456
Accumulated deficit	(553,587)	(378,630)
Accumulated other comprehensive loss	(68)	(48)
Total stockholders' equity	219,421	382,783
Total liabilities and stockholders' equity	$253,968	$409,154

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,	
	2017	2016	2017	2016
	(in thousands, except share and per share data)		(in thousands, except share and per share data)	
Revenues				
Collaboration and license agreements	$683	$113	$683	$113
Operating expenses				
Cost of sales	683	113	683	113
Research and development	65,276	33,833	155,965	61,480
General and administrative	9,548	6,466	19,529	12,511
Total operating expenses	75,507	40,412	176,177	74,104
Gain on license of clazakizumab	—	1,050	—	1,050
Loss from operations	(74,824)	(39,249)	(175,494)	(72,941)
Other income (expense)				
Interest income	438	529	923	944
Foreign currency loss	(113)	(146)	(107)	(232)
Total other income, net	325	383	816	712
Net loss before equity in net loss of unconsolidated entity	(74,499)	(38,866)	(174,678)	(72,229)
Equity in net loss of unconsolidated entity	(130)	—	(279)	—
Net loss	$(74,629)	$(38,866)	$(174,957)	$(72,229)
Net loss per share - basic and diluted	$(1.48)	$(0.79)	$(3.47)	$(1.55)
Weighted average number of common shares used in net loss per share - basic and diluted	50,427,865	49,284,573	50,411,837	46,519,045

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,	
	2017	2016	2017	2016
	(in thousands)		(in thousands)	
Net loss	$(74,629)	$(38,866)	$(174,957)	$(72,229)
Other comprehensive income (loss):				
Unrealized gain (loss) on securities available-for-sale, net of tax	(73)	146	(20)	560
Foreign currency translation income, net of tax	—	—	—	21
Total other comprehensive income (loss)	(73)	146	(20)	581
Comprehensive loss	$(74,702)	$(38,720)	$(174,977)	$(71,648)

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,	
	2017	2016
	(in thousands)	
Operating activities		
Net loss	$(174,957)	$(72,229)
Adjustments to reconcile net loss to net cash used in operating activities		
Non-cash gain on license of clazakizumab in exchange for investment in unconsolidated entity	—	(1,050)
Equity in net loss of unconsolidated entity	279	—
Depreciation and amortization	1,486	505
Stock-based compensation	10,901	6,348
Other non-cash charges, net	300	65
Changes in operating assets and liabilities		
Prepaid expenses and other assets	27,159	291
Inventory	—	(936)
Accounts payable	9,837	2,851
Accrued liabilities	(1,201)	111
Deferred rent	(58)	28
Net cash used in operating activities	(126,254)	(64,016)
Investing activities		
Purchases of investments	(28,334)	(55,613)
Proceeds from maturities of investments	166,973	10,250
Purchases of property and equipment	(1,526)	(2,953)
Proceeds from sale of property and equipment	—	5
Net cash provided by (used in) investing activities	137,113	(48,311)
Financing activities		
Proceeds from issuance of common stock, net of offering costs	—	134,871
Proceeds from exercise of stock options and employee stock purchase plan	714	979
Net cash provided by financing activities	714	135,850
Effect of exchange rate changes on cash	—	21
Net increase in cash and cash equivalents	11,573	23,544
Cash and cash equivalents		
Beginning of period	116,216	206,492
End of period	$127,789	$230,036
Supplemental disclosures:		
Purchases of property and equipment included in accounts payable and accrued liabilities	$101	$1,156

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 current treatment paradigms. 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.

Public Offerings

In April 2016, the Company completed an underwritten public offering of 6,182,795 shares of common stock, which included 806,451 shares the Company issued pursuant to the underwriters' exercise of their option to purchase additional shares. The Company received $134.9 million in net proceeds, after deducting underwriting discounts and commissions of $8.6 million and offering expenses of $0.3 million.

On July 18, 2017, the Company completed an underwritten public offering of 17,250,000 shares of common stock, which included 2,250,000 shares the Company issued pursuant to the underwriters' exercise of their option to purchase additional shares. The Company received approximately $161.5 million in net proceeds, after deducting underwriting discounts and commissions of $10.4 million and estimated offering expenses of $0.7 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. All inter-company balances and transactions have been eliminated in consolidation. The condensed consolidated balance sheet data as of December 31, 2016 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 (Bothell, WA), 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, 2016.

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, 2017 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 and short-term investments in excess of amounts insured by the Federal Deposit Insurance Corporation.

Other Non-Current Assets

As of December 31, 2016, other non-current assets included an $8.0 million fee paid to a third party to secure additional production capacity. Upon execution of a binding agreement in March 2017, this payment was characterized as a non-refundable payment and recognized as research and development expense during the first quarter ended March 31, 2017.

Liquidity and Going Concern

As disclosed in our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2017 (the "Q1 2017 Form 10-Q"), in accordance with the requirements of ASC 205-40, management concluded that it was required to disclose that substantial doubt existed about the Company's ability to continue as a going concern for one year from the date the financial statements included in the Q1 2017 Form 10-Q were issued. On July 18, 2017, the Company received approximately $161.5 million in net proceeds from an underwritten public offering of common stock. The Company also decreased its forecasted cash requirements for operating activities over the next year. The Company estimates the available cash, cash equivalents and investments as of June 30, 2017, together with the proceeds received from the July 2017 offering, will be sufficient to meet its projected operating requirements for at least the next twelve months from the filing date of these financial statements. As a result of these conditions and events, substantial doubt of the Company's ability to continue as a going concern no longer exists. The Company will need to obtain substantial additional funding to develop and commercialize eptinezumab and other clinical programs as currently contemplated. 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 May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update (ASU) No. 2014-09, Revenue from Contracts with Customers (Topic 606), which will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. This ASU stipulates that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The ASU also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. In March 2016, the FASB issued ASU 2016-08, Principal versus Agent Considerations (Reporting Revenue Gross versus Net). This ASU clarifies the implementation guidance on principal versus agent considerations. In April 2016, the FASB issued ASU 2016-10, Identifying Performance Obligations and Licensing. This ASU clarifies two aspects of ASU 2014-09, Revenue from Contracts with Customers (Topic 606): Identifying performance obligations and the licensing implementation guidance. In May 2016, the FASB issued ASU 2016-12, Narrow-Scope Improvements and Practical Expedients. This ASU addresses certain issues in ASU 2014-09, Revenue from Contracts with Customers (Topic 606) regarding assessing collectability, presentation of sales taxes, noncash consideration, and completed contracts and contract modifications at transition. In December 2016, the FASB issued ASU 2016-20, Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers. This ASU amends narrow aspects of ASU 2014-09, Revenue from Contracts with Customers.

The new revenue standards are effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period. Early adoption is permitted for annual reporting periods beginning after the original effective date of December 15, 2016. The standards permit the use of either the full retrospective or modified retrospective method. The Company does not believe adopting this guidance will have a material impact on its financial statements as the Company is not currently generating material revenues.

In January 2016, the FASB issued ASU 2016-01, Financial Instruments-Overall. This ASU addresses certain aspects of recognition, measurement, presentation, and disclosure of financial instruments. This ASU will become effective for annual periods beginning after December 15, 2017. The Company is currently evaluating the impact of the adoption of this ASU on its consolidated financial statements.

In February 2016, the 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. This ASU will become effective for annual periods beginning after December 15, 2018. The Company expects adopting this ASU will result in an increase in the assets and liabilities on its consolidated balance sheets and will have no impact on its consolidated statements of operations and statement of cash flows.

In August 2016, the FASB issued ASU 2016-15, Statement of Cash Flows – Classification of Certain Cash Receipts and Cash Payments. This ASU addresses eight specific cash flow issues with the objective of reducing the existing diversity in practice. This ASU will become effective for annual periods beginning after December 15, 2017. The Company does not believe adopting this ASU will have a material impact as it relates to the treatment of equity distributions which are currently not material to the Company.

In May 2017, the FASB issued ASU 2017-09, Compensation-Stock Compensation (Topic 718) – Scope of Modification Accounting. This ASU provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. This ASU will become effective for annual periods beginning after December 15, 2017. The Company is currently evaluating the impact of the adoption of this ASU 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 consolidated financial statements as a result of future adoption.

3. Net Loss Per Share

Basic net loss per share is calculated by dividing net loss 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,	
	2017	2016	2017	2016
Net loss (in thousands)	$(74,629)	$(38,866)	$(174,957)	$(72,229)
Denominator				
Weighted average common shares outstanding - basic and diluted	50,427,865	49,284,573	50,411,837	46,519,045
Net loss per share - basic and diluted	$(1.48)	$(0.79)	$(3.47)	$(1.55)

The following weighted average numbers of outstanding stock options and employee stock purchase plan awards were excluded from the calculation of diluted net loss per share for the three and six months ended June 30, 2017 and 2016 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,	
	2017	2016	2017	2016
Stock options	6,795,748	4,270,080	6,381,733	4,009,156
Employee stock purchase plan	61,354	22,814	116,887	43,511
	6,857,102	4,292,894	6,498,620	4,052,667

4. Short-term Investments

Short-term 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, 2017				
Negotiable certificates of deposit maturing in				
one year or less	$5,000	$ —	$ (1)	$4,999
U.S. government agency obligations maturing in				
one year or less	91,758	—	(65)	91,693
Total available-for-sale securities	$96,758	$ —	$ (66)	$96,692
Type of security as of December 31, 2016				
Negotiable certificates of deposit maturing in				
one year or less	$11,000	$ 1	$ (4)	$10,997
U.S. government agency obligations maturing in				
one year or less	224,697	27	(70)	224,654
Total available-for-sale securities	$235,697	$ 28	$ (74)	$235,651

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. There were no realized gains or losses on sales of available-for-sale securities in the three and six months ended June 30, 2017 and 2016.

5. 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, 2017				
Cash equivalents				
Money market funds	$95,063	$—	$ —	$95,063
Short-term investments				
Negotiable certificates of deposit	—	4,999	—	4,999
U.S. government agency obligations	—	91,693	—	91,693
	$95,063	$96,692	$ —	$191,755
As of December 31, 2016				
Cash equivalents				
Money market funds	$111,149	$—	$ —	$111,149
Short-term investments				
Negotiable certificates of deposit	—	10,997	—	10,997
U.S. government agency obligations	—	224,654	—	224,654
	$111,149	$235,651	$ —	$346,800

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.

6. Gain on License of Clazakizumab and Investment in Unconsolidated Entity

In May 2016, the Company licensed the exclusive worldwide rights to its product candidate clazakizumab to Vitaeris, Inc. ("Vitaeris"), based in Vancouver, British Columbia, that is pursuing innovative therapeutic indications in chronic inflammatory diseases. 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. In addition, Randall C. Schatzman, Ph.D., the Company's president and chief executive officer, joined Vitaeris' board of directors. 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. The

Company recognized an initial 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.

As of June 30, 2017, the Company held $0.9 million in inventory of finished goods related to clazakizumab on its condensed consolidated balance sheet. Clazakizumab has not received regulatory approval for commercial sale and the related inventory is currently held only for resale associated with the Vitaeris agreement. The Company values inventory at the lower of cost or market value which is determined using the specific identification basis. Inventory is reduced to net realizable value for excess, obsolete or unsalable inventory.

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 $0.1 million and $0.3 million in net loss with respect to Vitaeris for the three and six months ended June 30, 2017, respectively. The carrying value of the Company's investment in Vitaeris is $0.6 million as of June 30, 2017, which is classified as a non-current asset. 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.

7. Accrued Liabilities

Accrued liabilities consisted of the following for the dates indicated:

	June 30, 2017	December 31, 2016
	(in thousands)	
Compensation and benefits	$4,244	$ 4,833
Contracted research and development	8,574	9,837
Professional services and other	1,418	767
	$14,236	$ 15,437

8. Subsequent Event

On July 18, 2017, the Company completed an underwritten public offering of 17,250,000 shares of common stock, which included 2,250,000 shares the Company issued pursuant to the underwriters' exercise of their option to purchase additional shares. The Company received approximately $161.5 million in net proceeds, after deducting underwriting discounts and commissions of $10.4 million and estimated offering expenses of $0.7 million.

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, 2016 included in our Annual Report on Form 10-K, or 2016 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 current treatment paradigms. 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. Our infusion formulation of 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 second half of 2018. 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, approximately three million people live with chronic migraine, and another two million live with severe frequent episodic migraine. This segment of five million people living with migraine are the most highly-impacted patients, and they typically experience eight or more migraines per month. Current preventative migraine treatment options available in the market today are challenged by safety, efficacy and tolerability limitations. More than 40 percent of migraineurs have not used a preventative therapeutic, and only about one in 10 currently utilize a preventative therapeutic. 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, if approved, on this five million patient migraine segment. We estimate the market opportunity for eptinezumab infusion therapy is approximately $1.5 to $2.0 billion.

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 in-office infusion procedure, provides rapid and persistent migraine prevention. Eptinezumab is the only anti-CGRP monoclonal antibody in development for the prevention of migraine administered via infusion. 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.

In Phase 2 clinical trials for the prevention of migraine, after a single administration via infusion, eptinezumab has demonstrated:

1. Rapid speed to clinical benefit: Chronic migraine patients experienced a clinically meaningful reduction in the number of migraine days in as little as 24 to 48 hours. This means their migraine prevention benefit started as soon as 1-2 days

following treatment. In these trials, chronic and frequent episodic migraine patients experienced maximum efficacy in 1-4 weeks after a single dose of eptinezumab.
2. Efficacy: Approximately one-third of the patients in these trials experienced a 75 percent reduction in their number of migraine days each month starting 1-4 weeks after treatment.
3. Persistence of Response: Following a single administration of eptinezumab, the efficacy response that was attained within 1-4 weeks of the first dose was sustained for 3 months. This supports our proposed quarterly dosing regimen and our expectation that less frequent dosing will be needed with eptinezumab as compared to prevention therapies that may require monthly dosing.
4. Safety: Safety and tolerability similar to placebo.

We also believe that administration as a 30-minute, in-office infusion procedure may promote greater patient adherence and physician oversight relative to self-administered therapies.

The pivotal trial program for our infusion formulation of eptinezumab in support of a BLA submission consists of two Phase 3 pivotal trials and a single open-label Phase 3 clinical trial. Our first pivotal trial, PRevention Of Migraine via Intravenous ALD403 Safety and Efficacy 1 (PROMISE 1), commenced in October 2015 and is evaluating the safety and efficacy of eptinezumab administered via infusion once every 3 months for one year in 888 patients with frequent episodic migraine, defined as four to 14 migraine days per month. Our second pivotal trial, PRevention Of Migraine via Intravenous ALD403 Safety and Efficacy 2 (PROMISE 2), commenced in November 2016 and is evaluating the safety and efficacy of eptinezumab administered via infusion once every 3 months for six months in approximately 1,050 patients with chronic migraine, defined as 15 or more headache days per month, with features of migraine on at least eight days per month. The open-label trial commenced in December 2016 and is evaluating the long-term safety and tolerability of eptinezumab administered via infusion once every 3 months for one year in approximately 120 patients with chronic migraine. As described under "—Recent Developments", on June 27, 2017 we announced top-line results from PROMISE 1, showing that eptinezumab met the primary and key secondary endpoints. We expect top-line data from the PROMISE 2 open-label trial to be available in the first half of 2018. In May 2017, we obtained input from the FDA regarding data requirements necessary to support comparability between eptinezumab used in our clinical trials and our proposed commercial manufacturing of the drug. We currently anticipate that our data package will include, among other things, a study showing pharmacokinetic comparability between eptinezumab used in clinical trials and our commercial supply. Our objective is to submit a BLA to the FDA based on the results of our two Phase 3 pivotal trials and our open-label Phase 3 trial in the second half of 2018.

While we are focused on completing our current clinical program in support of a BLA submission for our infusion formulation of eptinezumab for chronic and frequent episodic migraine patients, we will consider other studies to continue building on the differentiating characteristics of eptinezumab aimed at achieving label enhancements. We are also committed to developing a subcutaneous mode for administering eptinezumab as part of our life cycle planning in order to maximize the value of eptinezumab.

Assuming eptinezumab is approved by the FDA, we plan to focus our initial commercialization efforts on high-prescribing neurologists and headache centers in the United States employing a specialty sales force of 75 to 125 people. We believe that these neurologists and headache centers treat the highest proportion of the five million chronic and severe frequent episodic migraine patients described above. This group consists of an estimated 3,000 migraine specialists, which we refer to as interventionalists, of whom we estimate 77 percent have previously prescribed infusion therapies for migraine and 63 percent have in-house infusion capabilities. We believe a significant number of these interventionalists are interested in growing their migraine procedure base and have infrastructure in place to handle patient flow, product supply and reimbursement support. 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. We also intend to seek approval for eptinezumab in the European Union and other jurisdictions outside the United States.

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 to clazakizumab to Vitaeris, Inc., or Vitaeris, based in Vancouver, British Columbia, that will pursue innovative therapeutic indications in chronic inflammatory diseases. Prior to the license to Vitaeris, clazakizumab completed two positive Phase 2b clinical trials establishing proof-of-concept in patients with rheumatoid arthritis.

Recent Developments

On June 27, 2017, we announced that eptinezumab met the primary and key secondary endpoints in PROMISE 1. This Phase 3 pivotal clinical trial is evaluating the safety and efficacy of eptinezumab administered at three dose levels (300mg, 100mg and 30mg) and placebo via infusion once every 3 months for one year in 888 patients with frequent episodic migraine. We believe these positive

results, consistent with previously reported eptinezumab studies, support the unique clinical profile of eptinezumab as a potential first-of-its-kind infusion therapy to prevent migraines.

The primary endpoint, demonstrating statistically significant reductions in monthly migraine days from baseline (average of 8.6 days) over months 1 through 3 (1 month = 28 days), was 4.3 monthly migraine days for 300mg (p=0.0001) and 3.9 days for 100mg (p=0.0179) compared to an average 3.2 days for placebo. The 30mg dose level was not formally tested as per the pre-specified statistical analysis plan.

Secondary endpoints evaluating time points through the first quarterly dose include:

- ≥75% reduction in monthly migraine days achieved over weeks 1 through 4 of 31.5% for 300mg (p=0.0066), and 30.8% for 100mg (p=0.0112) compared to 20.3% for placebo.
- ≥75% reduction in monthly migraine days achieved over months 1 through 3 of 29.7% for 300mg (p=0.0007), and 22.2% for 100mg (not statistically significant) compared to 16.2% for placebo.
- ≥50% reduction in monthly migraine days achieved by 56.3% of patients over months 1 through 3 for 300mg (p=0.0001), and 49.8% for 100mg (p=0.0085, unadjusted) compared to 37.4% for placebo.
- 53.6% reduction in the proportion of patients experiencing migraine on the day following administration at 300mg (p=0.0087, unadjusted), and 51.3% at 100mg (p=0.0167, unadjusted), compared to 20.7% for placebo. Though not a secondary endpoint, a post hoc analysis demonstrated that over weeks 1 through 4, the proportion of patients experiencing migraine was lowest on the day following administration (14.3% at 300mg and 15.1% at 100mg, respectively) and was sustained through week 4 (15.9% at 300mg and 17.2% at 100mg, respectively). This outcome was consistent with a post hoc analysis of data from our Phase 2b clinical trial in patients with chronic migraine demonstrating that the proportion of patients experiencing migraine on the day following administration was reduced by 54% at 300 mg, and 51% at 100 mg, compared to 17% for placebo. As with the PROMISE 1 data, over weeks 1 through 4, the proportion of patients experiencing migraine in the Phase 2b study was lowest on the day following administration (26.5% at 300mg and 29.3% at 100mg) and was sustained through week 4 (30.0% at 300mg and 100mg, respectively).

Secondary endpoints demonstrated responses that were improved through the second quarterly dose period, and include:

- ≥75% reduction in monthly migraine days achieved over months 4 through 6 of 40.1% for 300mg (p=0.0006, unadjusted), and 33.5% for 100mg (p=0.0434, unadjusted) compared to 24.8% for placebo.
- Average of one in five patients receiving 300mg (20.6%) had 100% responses with no migraines in any given month (months 1 through 6).

The observed safety profile in this study to date was similar to placebo. Both the safety profile and the placebo rates were consistent with previously reported eptinezumab studies. Full safety data will be available at the end of the study.

The statistical significance of the PROMISE 1 results for each dose level across endpoints was assessed in a hierarchy set forth in a pre-specified statistical analysis plan (generally assessing the 300mg dose level for a group of endpoints, 100mg dose level for a group of endpoints and 30mg dose level for a group of endpoints in sequence). Since the result for the 100mg dose level for the ≥75% reduction in monthly migraine days over months 1 through 3 endpoint was not statistically significant, the 30mg dose level was not formally tested per the statistical analysis plan.

Additional results, including future analysis of additional secondary endpoints, from the trial are expected to be presented at future medical meetings and published in peer-reviewed medical journals.

Corporate and Other Financial Information

We were incorporated in 2002 and have not generated any product revenue. Through June 30, 2017, our operations have been primarily funded by $621.8 million of net proceeds in public offerings, $111.4 million in private placements of our capital stock, and $135.0 million in upfront payments, milestones and research and development payments from our former collaborators and government grants.

As disclosed in our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2017, or the Q1 2017 Form 10-Q, in accordance with the requirements of ASC 205-40, management concluded that it was required to disclose that substantial doubt existed about the Company's ability to continue as a going concern for one year from the date the financial statements included in the Q1 2017 Form 10-Q were issued (i.e., the date the Q1 2017 Form 10-Q was filed with the SEC). On July 18, 2017, we received approximately $161.5 million in net proceeds from an underwritten public offering of common stock. We also decreased our forecasted cash requirements for operating activities over the next year. We believe that our available cash, cash equivalents and investments as of June 30, 2017, together with the proceeds received from the July 2017 offering, will be sufficient to meet our projected operating requirements for at least the next twelve months from the filing date of this report. As a result of these conditions and events, substantial doubt of our ability to continue as a going concern no longer exists.

We will not generate revenues from product sales unless and until we or our future collaborators successfully complete development and obtain regulatory approval for one or more of our product candidates, which we expect will take a number of years and is subject to significant uncertainty. If we obtain regulatory approval for eptinezumab, ALD1910 or any future product candidate, we expect to incur significant commercialization expenses related to sales, marketing, manufacturing and distribution to the extent that such costs are not paid by future collaborators. We will need to obtain substantial additional sources of funding to complete the clinical development of any of our product candidates and will require additional funding in order to complete the development activities required for regulatory approval of eptinezumab, ALD1910 or any future product candidates that we develop independently. In addition, our clinical trials for eptinezumab may encounter manufacturing, enrollment or other issues that could cause our development costs to increase more than we expect. If such additional funding is not available on favorable terms or at all, we may need to delay or reduce the scope of our development programs or grant rights in the United States, as well as outside the United States, to our product candidates to one or more partners.

Financial Operations Overview

Revenues and Cost of Sales

We recognized $0.7 million and $0.1 million in revenue and $0.7 million and $0.1 million in cost of sales in the three and six months ended June 30, 2017 and 2016, respectively, relating to the sale of drug supply inventory to Vitaeris at cost. 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 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 affairs activities.

We plan to increase our research and development expenses for the foreseeable future as we continue the development of eptinezumab and advance ALD1910 and our future product candidates into clinical development. 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; 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 also incur expenses of being a public company, including expenses related to compliance with the rules and regulations of the SEC, and those of the NASDAQ Stock Market LLC, or NASDAQ, additional insurance expenses, investor relations activities and other administrative and professional services.

Results of Operations

Comparison of the Three and Six Months Ended June 30, 2017 and 2016

Revenue and Cost of Sales

We recognized $0.7 million and $0.1 million in revenue and $0.7 million and $0.1 million in cost of sales in the three and six months ended June 30, 2017 and 2016, respectively, 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, 2017 and 2016 were as follows:

	Three Months Ended June 30,			Six Months Ended June 30,		
	2017	2016	% change	2017	2016	% change
	(dollars in thousands)			(dollars in thousands)		
External costs:						
Eptinezumab	$48,561	$21,484	126 %	$123,264	$35,774	245 %
ALD1613	—	2,008	(100 %)	—	5,813	(100 %)
ALD1910	937	—	—	1,596	—	—
Unallocated internal costs:						
Preclinical discovery and development	5,230	4,396	19 %	10,387	8,824	18 %
Pharmaceutical operations	5,761	4,358	32 %	11,551	8,335	39 %
Clinical development	4,787	1,587	202 %	9,167	2,734	235 %
Total research and development expenses	$65,276	$33,833	93 %	$155,965	$61,480	154 %

Research and development expenses increased by $31.4 million, or 93%, for the three months ended June 30, 2017 compared to the same period in 2016. During the three months ended June 30, 2017, external costs incurred for eptinezumab increased by $27.1 million, or 126%. The increased level of spending for eptinezumab was primarily due to an additional $19.6 million in manufacturing costs for commercial readiness activities and drug supply in support of planned and ongoing clinical trials and an additional $7.1 million in clinical trial costs. External costs for ALD1613 decreased $2.0 million because we terminated the development of this product candidate in mid-2016. External costs for ALD1910 increased by $0.9 million for IND-enabling activities. Unallocated internal costs also increased by $5.4 million due primarily to an increase in salaries expense of $2.3 million and an increase in stock-based compensation expense of $1.4 million in the three months ended June 30, 2017 as a result of a 37% increase in our research and development headcount to support our ongoing and planned clinical trials and other development activities.

Research and development expenses increased by $94.5 million, or 154%, for the six months ended June 30, 2017 compared to the same period in 2016. During the six months ended June 30, 2017, external costs incurred for eptinezumab increased by $87.5 million, or 245%. The increased level of spending for eptinezumab was primarily due to an additional $71.0 million in manufacturing costs for commercial readiness activities and drug supply in support of planned and ongoing clinical trials and an additional $15.5 million in clinical trial costs. External costs for ALD1613 decreased $5.8 million because we terminated the development of this product candidate in mid-2016. External costs for ALD1910 increased by $1.6 million as we continued to advance the program. Unallocated internal costs also increased by $11.2 million due primarily to an increase in salaries expense of $5.2 million, an increase in stock-based compensation expense of $2.5 million and an increase in facilities-related expenses of $1.4 million in the six months ended June 30, 2017 as a result of a 43% increase in our research and development headcount to support our ongoing and planned clinical trials and other development activities. Costs incurred for medical affairs, professional fees and consulting increased $1.6 million to support our programs.

General and Administrative Expenses

General and administrative expenses increased by $3.1 million, or 48%, for the three months ended June 30, 2017 compared to the same period of 2016. The increase was primarily due to an increase in stock-based compensation expense of $1.0 million, an increase of $0.8 million in salaries expense due to a 41% increase in headcount, and an increase of $1.3 million in professional fees and other administrative costs primarily to support commercial readiness activities.

General and administrative expenses increased by $7.0 million, or 56%, for the six months ended June 30, 2017 compared to the same period of 2016. The increase was primarily due to an increase in stock-based compensation expense of $2.0 million, an increase of $1.6 million in salaries expense due to a 46% increase in headcount, and an increase of $3.4 million in professional fees and other administrative costs primarily to support commercial readiness activities. We anticipate increases in general and administrative expenses for commercial marketing as we build out our commercial readiness infrastructure and product launch plans for eptinezumab.

Interest Income

The decrease in interest income for the three and six months ended June 30, 2017 was primarily due to a lower average cash balance compared to the same period of 2016.

Gain on License of Clazakizumab

In May 2016, we licensed the exclusive worldwide rights to clazakizumab to Vitaeris. We did not recognize any gain on the license of clazakizumab in the three and six months ended June 30, 2017. We recognized a gain on the license agreement of $1.1 million in the three and six months ended June 30, 2016.

Foreign Currency 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 loss of $0.1 million in both the three and six months ended June 30, 2017 and a net foreign currency loss of $0.1 million and $0.2 million in the same periods of 2016, respectively, due primarily to fluctuations in both years in the exchange rates of the British pound relative to the U.S. dollar.

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. 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. We did not record any loss or income generated by Vitaeris in the three and six months ended June 30, 2016.

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 and payments from our former collaboration partners. As of June 30, 2017, we had an accumulated deficit of $553.6 million and cash, cash equivalents and short-term investments on hand of $224.5 million, which consisted of cash, money market funds, negotiable certificates of deposit and U.S. government agency obligations. On July 18, 2017, we completed an underwritten public offering of 17,250,000 shares of common stock resulting in net proceeds of approximately $161.5 million, after deducting underwriting discounts, commissions and estimated offering expenses. 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 investments as of June 30, 2017, together with the proceeds received from the July 2017 offering, will be sufficient to meet our projected operating requirements for at least the next twelve months from the filing date of this report. 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. Furthermore, our operating plans may change, and we may need additional funds to meet operational needs and capital requirements for product development and commercialization sooner than planned. We will also need to obtain substantial additional sources of funding to develop and commercialize eptinezumab and other clinical programs as currently contemplated. 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. 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,	
	2017	2016
Net cash used in operating activities	$(126,254)	$(64,016)
Net cash provided by (used in) investing activities	137,113	(48,311)
Net cash provided by financing activities	714	135,850

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 $126.3 million in the six months ended June 30, 2017 compared to $64.0 million during the same period in 2016. The $62.2 million increase in net cash used in operating activities in the six months ended June 30, 2017 compared to the same period in 2016 was driven primarily by an increase in net loss of $102.7 million, of which $29.4 million was due to the recognition of manufacturing expenses in support of our commercial readiness activities for eptinezumab which were prepaid at December 31, 2016 and therefore did not use cash in the six months ended June 30, 2017. Other changes which also increased cash used in operating activities compared to the prior year period were an increase in stock-based compensation of $4.6 million due to increases in headcount to support our programs under development, and an increase in the change in accounts payable of $7.0 million which was offset by a decrease of $1.3 million in the change in accrued liabilities.

Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities was $137.1 million in the six months ended June 30, 2017, compared to net cash used in investing activities of $48.3 million during the same period in 2016. The increase of $185.4 million in net cash provided by investing activities was primarily due to the maturities of investments offset by fewer purchases of investments. Purchases of property and equipment used cash of $1.5 million and $3.0 million in the six months ended June 30, 2017 and 2016, respectively. We anticipate a reduction in capital expenditures during 2017 compared to 2016.

Cash Provided by Financing Activities

Net cash provided by financing activities were $0.7 million in the six months ended June 30, 2017 due to the exercise of stock options and purchases under the employee stock purchase plan. Net cash provided by financing activities were $135.9 million in the six months ended June 30, 2016 due to the April 2016 public offering in which we received proceeds of $134.9 million net of underwriting discounts, commissions and offering costs and $1.0 million from 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, 2017.

Contractual Obligations

Our contractual obligations as of June 30, 2017 were as follows:

	Total	Less Than 1 Year	1-3 Years	3-5 Years	More Than 5 Years
	(in thousands)				
Operating lease obligations[1]	$9,016	$ 1,315	$4,431	$ 3,270	$ —
License agreements[2]	625	50	150	150	275
Purchase obligations[3]	16,902	16,902	—	—	—
Contract manufacturing obligations[4]	207,168	72,037	106,696	28,435	—
Total contractual obligations	$233,711	$ 90,304	$111,277	$ 31,855	$ 275

(1) 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.
(2) 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.
(3) 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.
(4) 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, 2017 under agreements with third-party contract manufacturing organizations for larger scale production of eptinezumab. 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.

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 U.S. 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.

There have been no significant and material changes in our critical accounting policies during the six months ended June 30, 2017, 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 2016 Form 10-K. We believe that the accounting policies discussed in our 2016 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, 2017, we had cash, cash equivalents and short-term investments of $224.5 million consisting of cash, money market accounts, negotiable certificates of deposit in highly rated financial institutions in the United States 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 $0.2 million in the fair value of our investments as of June 30, 2017. In addition, a hypothetical decrease of 10% in the effective yield of our investments would reduce our expected investment income by approximately $0.2 million over the next twelve months based on our investment balance at June 30, 2017.

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 various countries in Europe. Our foreign subsidiaries in Australia and Ireland also maintain bank accounts in their local currencies which are Australian dollars and Euros. We generally transfer funds to our Australian subsidiary and our Irish subsidiary to fund operating needs within 30 days of disbursement. We are subject to exposure due to fluctuations in foreign exchange rates in connection with these currencies, as well as fluctuations in British pounds and Swiss francs. 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, 2017, we held the U.S. dollar equivalent of $3.2 million in British pounds and approximately $0.9 million in other foreign currencies. A hypothetical 10% change in the exchange rate between the U.S. dollar and the British pounds, Swiss francs, Australian dollars, and Euros from the June 30, 2017 rate would have increased/decreased our total unrealized foreign currency loss on our holdings by approximately $0.4 million. For the three and six months ended June 30, 2017, our net foreign currency loss was not material.

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, 2017 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

On June 12, 2017, we submitted our statement setting out the grounds of appeal with respect to the decision of the Opposition Division, or OD, of the European Patent Office, or EPO, in the opposition to Labrys Biologics Inc.'s (owned by Teva Pharmaceutical Industries Ltd., or Teva) European Patent No. 1957106 B1 disclosed in "Item 3. Legal Proceedings" in our 2016 Form 10-K and in "Item 1. Legal Proceedings" in our Q1 2017 Form 10-Q. We previously filed our notice of appeal in the proceeding on March 31, 2017. Eli Lilly and Company and Teva have also appealed the OD's decision. We continue to firmly believe that the use claims that were maintained and narrowed by the OD were nevertheless improperly granted by the EPO and upheld by the OD, and should be revoked in their entirety on appeal for the reasons set forth in our grounds of appeal. There were no other material changes with respect to such matters 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, 2017, our net loss was $175.0 million, and as of June 30, 2017, we had an accumulated deficit of $553.6 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 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 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;
- 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, 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. We will need to obtain substantial additional sources of funding to develop and commercialize eptinezumab and other clinical programs as currently contemplated. If such additional funding is not available on favorable terms or at all, we may need to delay or reduce the scope of our eptinezumab development program or grant rights in the United States, as well as outside the United States, to eptinezumab to one or more partners. As disclosed in our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2017, or the Q1 2017 Form 10-Q, in accordance with the requirements of ASC 205-40, management concluded that it was required to disclose that substantial doubt existed about the Company's ability to continue as a going concern for one year from the date the financial statements included in the Q1 2017 Form 10-Q were issued (i.e., the date the Q1 Form 10-Q was filed with the SEC). As of June 30, 2017, we had $224.5 million in cash, cash equivalents and short-term investments. On July 18, 2017, we completed an underwritten public offering of 17,250,000 shares of common stock resulting in net proceeds of $161.5 million, after deducting underwriting discounts, commissions, and estimated offering expenses. We also decreased our forecasted cash requirements for operating activities over the next year. We believe that our available cash, cash equivalents and investments as of June 30, 2017, together with the proceeds received from the July 2017, offering will be sufficient to meet our projected operating requirements for at least the next twelve months from the filing date of this report. As a result of these conditions and events, substantial doubt of our ability to continue as a going concern no longer exists.

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;

- 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.

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.

In addition, our clinical trials for eptinezumab may encounter manufacturing, enrollment or other issues that could cause our development costs to increase more than we expect. We do not have sufficient cash to complete the clinical development of any of our product candidates and will require additional funding in order to complete the development activities required for regulatory approval of eptinezumab, ALD1910 or any future product candidates that we develop independently. We intend to prioritize our development efforts on eptinezumab, both in terms of funding and attention of management and our organization. Because successful development of our product candidates is uncertain, we are unable to estimate the actual funds we will require to complete research and development and commercialize our product candidates.

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 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, 2016, we had U.S. net operating loss carryforwards, or NOLs, of $379.9 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 $13.1 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 2015 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.

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 any clinical trials for our commercial supply of eptinezumab that maybe necessary 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 commercial manufacturing arrangements 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;
- effectively competing with other therapies;
- 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 any clinical trials for our commercial supply of eptinezumab that may be necessary 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 frequent episodic and chronic migraines, and no approved drug procedure for prevention for frequent 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 frequent 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 frequent episodic migraine. There are also several other companies, Amgen, Lilly and Teva, that are developing CGRP blocking therapies using monoclonal antibodies similar to eptinezumab designed for subcutaneous administration by patients. 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. We are aware that Amgen, Lilly and Teva have each announced that they plan to make BLA submissions in 2017 for their competing CGRP therapies, which, if approved, would enable them to commercialize their CGRP 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.

For example, our ongoing PROMISE 2 trial of eptinezumab for the prevention of chronic migraine is currently expected to enroll approximately 1,050 patients. We can provide no assurance that we will be able to enroll patients in PROMISE 2 or any other 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.

With respect to eptinezumab, the observed SAEs to date include, among others, inguinal hernia, kidney infection, transient ischemic attack, which is a precursor to stroke, conversion disorder, which is a mental health condition in which a person has blindness, paralysis, or other nervous system symptoms that cannot be explained by medical evaluation, chest pain, shortness of breath and wound infection. 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 currently rely on a single CMO to manufacture and provide us with clinical supplies of eptinezumab. We have entered into agreements with two other CMOs in anticipation of larger scale commercial production, and will use eptinezumab produced by these CMOs in future clinical studies. We expect to enter into agreements with additional CMOs in the future. 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 currently rely on Ajinomoto Althea Inc. to manufacture and provide us with clinical supplies of eptinezumab. We have entered into agreements with other manufacturers for larger scale production in anticipation of commercialization, and will use eptinezumab produced by these CMOs in future clinical studies. We expect to enter into agreements with additional CMOs in the future. 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 we and our suppliers cannot agree to the terms and conditions for provision of the drug product necessary for our clinical and commercial supply needs, or if a manufacturer terminates their agreement in response to a breach by us or otherwise becomes unable to fulfill its supply obligations, 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. In May 2017, we obtained input from the FDA regarding data requirements necessary to support comparability between eptinezumab used in our studies and our proposed commercial manufacturing of the drug. We currently anticipate that our data package will include, among other things, a study showing pharmacokinetic comparability between eptinezumab used in clinical trials and our commercial supply.

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 are using our proprietary antibody platform for the selection and manufacturing of monoclonal antibodies. We used this platform to create eptinezumab, ALD1910 and the 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;

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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;

- 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 March 2017, following the passage of a budget resolution for fiscal year 2017, the U.S. House of Representatives passed legislation known as the American Health Care Act, which, if enacted, would have amended or repealed significant portions of the ACA. Significant action by both houses of Congress to repeal and replace ACA continues to progress. 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;

- HIPPA, 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.

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 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. In addition, we are currently appealing a decision in an opposition proceeding involving the granted European patent of one of our potential competitors.

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. We are aware of third-party patents and patent applications containing granted claims relating to CGRP antibodies and the therapeutic use of CGRP antibodies to treat conditions including migraine. Furthermore, since patent applications are published some time after filing, and because applications can take several years to issue, there may be additional currently 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. For example, in July 2014, we and Eli Lilly and Company each filed an opposition to a European patent issued to Teva (Labrys) requesting that such patent be revoked in its entirety. In an oral proceeding held in Munich, Germany on November 18, 2016, the Opposition Division, or OD, of the European Patent Office, or EPO, issued a ruling revoking all claims in the patent relating to CGRP antagonist antibodies and maintaining but narrowing claims relating to the use of CGRP antagonist antibodies in human therapy to the prevention or treatment of headache such as migraine and cluster headache. The written decision consistent with the oral ruling was issued in February 2017. We are pursuing an appeal based on our continued firm belief that the patent claims that were maintained and narrowed were nevertheless improperly granted by the EPO and upheld by the OD, and should be revoked in their entirety on appeal for the reasons set forth in the opposition. For the reasons set forth in our opposition, we continue to firmly believe the patent should be revoked in its entirety. However, we cannot predict the specific timing or outcome of events or matters described above, or the impact of the November 18, 2016 decision on our business. On March 31, 2017, we filed a notice of appeal with the OD. On June 12, 2017, we submitted our statement setting out the grounds of appeal with respect to the decision of the OD of the EPO in the opposition to such patent. Eli Lilly and Company and Teva have also appealed the OD's decision. We plan to take action seeking to invalidate certain granted and pending Teva (Labrys) U.S. applications.

Because of the inevitable uncertainty in intellectual property legal proceedings, the European opposition appeal referenced above, or any other future proceeding, 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.

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 Common Stock

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
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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.

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 $9.30 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 $9.30 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 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.

Substantial future sales of shares of our common stock could cause the market price of our common stock to decline. This could cause the market price of our common stock 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 and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that such sales may have on the prevailing market price of our common stock.

In addition, as of June 30, 2017, we had options outstanding that, if fully exercised, would result in the issuance of 6,964,427 shares of common stock. As of June 30, 2017, there were also 1,958,564 shares of common stock reserved for future issuance under our 2014 Equity Incentive Plan and 1,249,093 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. All of the shares of common stock issuable pursuant to our equity compensation plans have been 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.

Moreover, as of June 30, 2017, holders of an aggregate of up to approximately 3.7 million shares 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.

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 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.

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

See the Exhibit Index immediately following the signature page to this Quarterly Report on Form 10-Q, which is incorporated by reference here.

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 8, 2017 By: /s/ Randall C. Schatzman
Randall C. Schatzman
President and Chief Executive Officer
(Principal Executive Officer)

Alder BioPharmaceuticals, Inc.

Date: August 8, 2017 By: /s/ Larry K. Benedict
Larry K. Benedict
Executive Vice President and Principal Accounting Officer
(Principal Financial and Accounting Officer)

EXHIBIT INDEX

Number	Description
3.1[(1)]	Amended and Restated Certificate of Incorporation of Alder BioPharmaceuticals, Inc.
3.2[(2)]	Amended and Restated Bylaws of Alder BioPharmaceuticals, Inc.
4.1[(3)]	Amended and Restated Investors' Rights Agreement, dated as of April 16, 2012, by and among Alder BioPharmaceuticals, Inc. and certain of its stockholders.
4.2[(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.
4.3[(4)]	Form of Common Stock Certificate.
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a).
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a).
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.
101.INS**	XBRL Instance Document.
101.SCH**	XBRL Taxonomy Extension Schema Document.
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF**	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document.

101.PRE** XBRL Taxonomy Extension Presentation Linkbase Document.

(1) Previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 13, 2014 (File No. 001-36431) and incorporated herein by reference.
(2) Previously filed as an exhibit to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-194672), filed with the Securities and Exchange Commission on April 25, 2014 and incorporated herein by reference.
(3) Previously filed as an exhibit to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-194672), filed with the Securities and Exchange Commission on March 19, 2014 and incorporated herein by reference.
(4) Previously filed as an exhibit to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-201201), filed with the Securities and Exchange Commission on December 22, 2014 and incorporated herein by reference.

* 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, 2017 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.