INCYTE CORP
Form 10-Q
October 31, 2017
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 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: 001-12400

INCYTE CORPORATION

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)	94-3136539 (IRS Employer Identification No.)
1801 Augustine Cut-Off Wilmington, DE 19803 (Address of principal executive offices)	 19803 (Zip Code)

(302) 498-6700

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a 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

The number of outstanding shares of the registrant's Common Stock, $.001 par value, was 211,037,309 as of October 25, 2017.

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PART I: FINANCIAL INFORMATION

Item 1. Financial Statements

INCYTE CORPORATION

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except number of shares and par value)

	September 30, 2017 (unaudited)	December 31, 2016*
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,128,046	$ 652,343
Marketable securities—available-for-sale	153,343	156,203
Accounts receivable	198,345	148,758
Inventory	3,261	4,106
Prepaid expenses and other current assets	58,327	32,768
Total current assets	1,541,322	994,178
Restricted cash and investments	926	886
Long term investments	169,020	31,987
Inventory	11,297	15,193
Property and equipment, net	246,825	167,679
Other intangible assets, net	242,285	258,437
In-process research and development	—	12,000
Goodwill	155,593	155,593
Other assets, net	7,033	2,644
Total assets	$ 2,374,301	$ 1,638,597
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 69,933	$ 75,599
Accrued compensation	61,274	50,904
Interest payable	100	762
Accrued and other current liabilities	164,298	126,697
Acquisition-related contingent consideration	24,330	19,539
Total current liabilities	319,935	273,501
Convertible senior notes	23,711	651,481
Acquisition-related contingent consideration	259,670	281,461
Other liabilities	13,235	12,687

Total liabilities	616,551	1,219,130
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; none issued or outstanding as of September 30, 2017 and December 31, 2016	—	—
Common stock, $0.001 par value; 400,000,000 shares authorized; 211,019,366 and 188,848,752 shares issued and outstanding as of September 30, 2017 and December 31, 2016, respectively	211	189
Additional paid-in capital	3,585,403	2,096,929
Accumulated other comprehensive income (loss)	12,512	(2,886)
Accumulated deficit	(1,840,376)	(1,674,765)
Total stockholders' equity	1,757,750	419,467
Total liabilities and stockholders' equity	$ 2,374,301	$ 1,638,597

* The condensed consolidated balance sheet at December 31, 2016 has been derived from the audited financial statements at that date.

See accompanying notes.

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INCYTE CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited, in thousands, except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Revenues:				
Product revenues, net	$ 322,029	$ 236,623	$ 878,503	$ 632,006
Product royalty revenues	44,487	29,626	108,477	77,486
Contract revenues	15,000	3,214	105,000	69,643
Other revenues	18	6	80	86
Total revenues	381,534	269,469	1,092,060	779,221
Costs and expenses:				
Cost of product revenues (including definite-lived intangible amortization)	22,036	20,205	57,120	38,577
Research and development	269,612	143,184	879,423	420,276
Selling, general and administrative	91,271	75,776	268,577	207,166
Change in fair value of acquisition-related contingent consideration	(16,343)	8,012	(1,914)	10,283
Total costs and expenses	366,576	247,177	1,203,206	676,302
Income (loss) from operations	14,958	22,292	(111,146)	102,919
Interest and other income, net	5,555	1,188	10,884	3,818
Interest expense	(204)	(9,479)	(6,527)	(29,275)
Unrealized gain (loss) on long term investments	23,045	24,301	(2,343)	20,497
Expense related to senior note conversions	—	—	(54,881)	—
Income (loss) before provision (benefit) for income taxes	43,354	38,302	(164,013)	97,959
Provision (benefit) for income taxes	7,300	1,425	(500)	2,610
Net income (loss)	$ 36,054	$ 36,877	$ (163,513)	$ 95,349
Net income (loss) per share:				
Basic	$ 0.17	$ 0.20	$ (0.81)	$ 0.51
Diluted	$ 0.17	$ 0.19	$ (0.81)	$ 0.49
Shares used in computing net income (loss) per share:				

Basic	206,796	188,029	202,399	187,632
Diluted	212,610	194,265	202,399	193,754

See accompanying notes.

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INCYTE CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(in thousands)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Net income (loss)	$ 36,054	$ 36,877	$ (163,513)	$ 95,349
Other comprehensive income:				
Foreign currency translation	(3)	(18)	(46)	(15)
Unrealized gain (loss) on marketable securities and long term investment, net of tax	1,501	(254)	15,305	1,036
Reclassification adjustment for realized loss on marketable securities	—	—	—	178
Defined benefit pension obligations, net of tax	46	—	139	—
Other comprehensive income (loss)	1,544	(272)	15,398	1,199
Comprehensive income (loss)	$ 37,598	$ 36,605	$ (148,115)	$ 96,548

See accompanying notes.

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INCYTE CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	Nine Months Ended September 30,	
	2017	2016
Cash flows from operating activities:		
Net income (loss)	$ (163,513)	$ 95,349
Adjustments to reconcile net income (loss) to net cash (used in) provided by operating activities:		
Depreciation and amortization	39,319	40,859
In-process research and development impairment	12,000	—
Stock-based compensation	99,287	68,598
Expense related to senior note conversions	54,881	—
Other, net	216	325
Unrealized loss (gain) on long term investments	2,343	(20,497)
Change in fair value of acquisition-related contingent consideration	(1,914)	10,283
Changes in operating assets and liabilities:		
Accounts receivable	(49,587)	(6,712)
Prepaid expenses and other assets	(32,051)	(13,323)
Inventory	4,741	4,439
Accounts payable	(5,666)	25,683
Accrued and other liabilities	36,223	15,018
Deferred revenue—collaborative agreements	—	(9,644)
Net cash (used in) provided by operating activities	(3,721)	210,378
Cash flows from investing activities:		
Acquisition of business, net of cash acquired	—	(142,965)
Purchase of long term investments	(123,891)	—
Capital expenditures	(85,770)	(104,405)
Purchases of marketable securities	(131,919)	(26,921)
Sale and maturities of marketable securities	134,604	77,815
Net cash used in investing activities	(206,976)	(196,476)
Cash flows from financing activities:		
Restricted investments, net	(40)	13,976
Proceeds from issuance of common stock under stock plans	58,554	32,468
Proceeds from issuance of common stock, net	649,387	—
Cash paid in connection with senior note conversions	(8,934)	—
Direct financing arrangements repayments	—	(445)
Payment of contingent consideration	(12,521)	(1,226)
Net cash provided by financing activities	686,446	44,773
Effect of exchange rates on cash and cash equivalents	(46)	(15)
Net increase in cash and cash equivalents	475,703	58,660
Cash and cash equivalents at beginning of period	652,343	521,439

Cash and cash equivalents at end of period	$ 1,128,046	$ 580,099
Supplemental Schedule of Cash Flow Information		
Interest paid	$ 180	$ 3,892
Income taxes paid	$ 6,187	$ 717
Reclassification to common stock and additional paid in capital in connection with conversions of 0.375% convertible senior notes due 2018	$ 351,041	$ 5
Reclassification to common stock and additional paid in capital in connection with conversions of 1.25% convertible senior notes due 2020	$ 330,011	$ 4
Unpaid purchases of property and equipment	$ 10,774	$ 6,989

See accompanying notes.

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INCYTE CORPORATION

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2017

(Unaudited)

1. Organization and business

Incyte Corporation (including its subsidiaries, "Incyte," "we," "us," or "our") is a biopharmaceutical company focused on developing and commercializing proprietary therapeutics. Our portfolio includes compounds in various stages, ranging from preclinical to late stage development, and commercialized products JAKAFI® (ruxolitinib) and ICLUSIG® (ponatinib). Our operations are treated as one operating segment.

2. Summary of significant accounting policies

Basis of presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. The condensed consolidated balance sheet as of September 30, 2017 and the condensed consolidated statements of operations, and comprehensive income (loss) for the three and nine months ended September 30, 2017 and 2016, and the condensed consolidated statement of cash flows for the nine months ended September 30, 2017 and 2016 are unaudited, but include all adjustments, consisting only of normal recurring adjustments, which we consider necessary for a fair presentation of the financial position, operating results and cash flows for the periods presented. The condensed consolidated balance sheet at December 31, 2016 has been derived from audited financial statements.

On June 1, 2016, we acquired (the "Acquisition"), pursuant to a Share Purchase Agreement dated as of May 9, 2016 (the "Share Purchase Agreement"), all of the outstanding shares of ARIAD Pharmaceuticals (Luxembourg) S.à.r.l., since renamed Incyte Biosciences Luxembourg S.à.r.l., the parent company of certain European subsidiaries of ARIAD Pharmaceuticals, Inc. ("ARIAD"). Refer to Note 3 for further information regarding the Acquisition.

Although we believe that the disclosures in these financial statements are adequate to make the information presented not misleading, certain information and footnote information normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP") have been condensed or omitted pursuant to the rules and regulations of the Securities and Exchange Commission.

Results for any interim period are not necessarily indicative of results for any future interim period or for the entire year. The accompanying financial statements should be read in conjunction with the financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2016.

Principles of Consolidation. The condensed consolidated financial statements include the accounts of Incyte Corporation and our wholly owned subsidiaries. All inter-company accounts, transactions, and profits have been eliminated in consolidation.

Acquisitions. Acquired businesses are accounted for using the acquisition method of accounting, which requires that assets acquired and liabilities assumed be recorded at fair value, with limited exceptions. Any excess of the purchase price over the fair value of the net assets acquired is recorded as goodwill. Transaction costs are expensed as incurred. The operating results of the acquired business are reflected in our consolidated financial statements after the date of acquisition. Acquired in-process research and development ("IPR&D") is recognized at fair value and initially characterized as an indefinite-lived intangible asset, irrespective of whether the acquired IPR&D has an alternative future use.

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Foreign Currency Translation. Operations in non-U.S. entities are recorded in the functional currency of each entity. For financial reporting purposes, the functional currency of an entity is determined by a review of the source of an entity's most predominant cash flows. The results of operations for any non-U.S. dollar functional currency entities are translated from functional currencies into U.S. dollars using the average currency rate during each month. Assets and liabilities are translated using currency rates at the end of the period. Adjustments resulting from translating the financial statements of our foreign entities that use their local currency as the functional currency into U.S. dollars are reflected as a component of other comprehensive income (loss). Transaction gains and losses are recorded in interest and other income, net in the condensed consolidated statements of operations. To date, both the translation gains or losses in other comprehensive income (loss) and the transaction gains or losses in foreign exchange gain (loss) have been immaterial.

Use of Estimates. The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

Concentrations of Credit Risk. Cash, cash equivalents, marketable securities, trade receivables and restricted investments are financial instruments which potentially subject us to concentrations of credit risk. The estimated fair value of financial instruments approximates the carrying value based on available market information. We primarily invest our excess available funds in debt securities and, by policy, limit the amount of credit exposure to any one issuer and to any one type of investment, other than securities issued or guaranteed by the U.S. government and money market funds that meet certain guidelines. Our receivables mainly relate to our product sales of JAKAFI, ICLUSIG and collaborative agreements with pharmaceutical companies. We have not experienced any significant credit losses on cash, cash equivalents, marketable securities, trade receivables or restricted investments to date and do not require collateral on receivables.

Cash and Cash Equivalents. Cash and cash equivalents are held in banks or in custodial accounts with banks. Cash equivalents are defined as all liquid investments and money market funds with maturity from date of purchase of 90 days or less that are readily convertible into cash.

Marketable Securities—Available-for-Sale. Available-for-sale securities are carried at fair value, based on quoted market prices and observable inputs, with unrealized gains and losses, net of tax, reported as a separate component of stockholders' equity. We classify marketable securities that are available for use in current operations as current assets on the condensed consolidated balance sheets. Realized gains and losses and declines in value judged to be other than temporary for available-for-sale securities are included in "Interest and other income, net." The cost of securities sold is based on the specific identification method.

Accounts Receivable. As of September 30, 2017 and December 31, 2016, we had no allowance for doubtful accounts. We provide an allowance for doubtful accounts based on experience and specifically identified risks. Accounts receivable are carried at fair value and charged off against the allowance for doubtful accounts when we determine that recovery is unlikely and we cease collection efforts.

Inventory. Inventories are determined at the lower of cost and net realizable value with cost determined under the specific identification method and may consist of raw materials, work in process and finished goods.

JAKAFI raw materials and work-in-process inventory is not subject to expiration and the shelf life of finished goods inventory is 36 months from the start of manufacturing of the finished goods. ICLUSIG raw materials and work-in-process inventory is not subject to expiration and finished goods inventory has a shelf life of 24 months from the start of manufacturing of the finished goods. We evaluate for potential excess inventory by analyzing current and future product demand relative to the remaining product shelf life. We build demand forecasts by considering factors

such as, but not limited to, overall market potential, market share, market acceptance and patient usage. We classify inventory as current on the condensed consolidated balance sheets when we expect inventory to be consumed for commercial use within the next twelve months.

The ICLUSIG inventories were recorded at fair value less costs to sell in connection with the Acquisition, which resulted in a higher cost of ICLUSIG product revenues over a one year period from the acquisition date.

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Variable Interest Entities. We perform an initial and on-going evaluation of the entities with which we have variable interests, such as equity ownership, in order to identify entities (i) that do not have sufficient equity investment at risk to permit the entity to finance its activities without additional subordinated financial support or (ii) in which the equity investors lack an essential characteristic of a controlling financial interest as variable interest entities ("VIE" or "VIEs"). If an entity is identified as a VIE, we perform an assessment to determine whether we have both (i) the power to direct activities that most significantly impact the VIE's economic performance and (ii) have the obligation to absorb losses from or the right to receive benefits of the VIE that could potentially be significant to the VIE. If both of these criteria are satisfied, we are identified as the primary beneficiary of the VIE. As of September 30, 2017, there were no entities in which we held a variable interest which we determined to be VIEs.

Long Term Investments. Our long term investments consist of investments in common stock of publicly held companies with whom we have entered into collaboration and license agreements. The investments in companies over which we have significant influence, but not controlling interest, are accounted for using the equity method (fair value option). The investments in companies over which we do not have significant influence are accounted for as available-for-sale securities. We classify all of our investments in common stock of publicly held companies with whom we have entered into collaboration and license agreements as long term investments, given we intend to hold these investments for the foreseeable future.

Equity Method Investments. In circumstances where we have the ability to exercise significant influence over the operating and financial policies of a company in which we have an investment, the investment is accounted for either (i) under the equity method of accounting or (ii) at fair value by electing the fair value option under U.S. GAAP. In assessing whether we exercise significant influence, we consider the nature and magnitude of our investment, any voting and protective rights we hold, 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, we record within our results of operations our share of income or loss of the investee company. Under the fair value option, our investment is carried at fair value on our condensed consolidated balance sheets as a long term investment and all changes in fair value are reported in our condensed consolidated statements of operations as an unrealized gain (loss) on long term investments.

Property and Equipment. Property and equipment is stated at cost, less accumulated depreciation and amortization. Depreciation is recorded using the straight-line method over the estimated useful lives of the respective assets. Leasehold improvements are amortized over the shorter of the estimated useful life of the assets or lease term.

Management continually reviews the estimated useful lives of technologically sensitive equipment and believes that those estimates appropriately reflect the current useful life of our assets. In the event that a currently unknown significantly advanced technology became commercially available, we would re-evaluate the value and estimated useful lives of our existing equipment, possibly having a material impact on the financial statements.

Lease Accounting. We account for operating leases by recording rent expense on a straight-line basis over the expected life of the lease, commencing on the date we gain possession of leased property. We include tenant improvement allowances and rent holidays received from landlords and the effect of any rent escalation clauses to determine the straight-line rent expense over the expected life of the lease.

Capital leases are reflected as a liability at the inception of the lease based on the present value of the minimum lease payments or, if lower, the fair value of the property. Assets under capital leases are recorded in property and equipment, net on the condensed consolidated balance sheets and depreciated in a manner similar to other property and equipment.

Other Intangible Assets, net. Other intangible assets, net consist of licensed intellectual property rights acquired in business combinations, which are reported at fair value, less accumulated amortization. Intangible assets with finite lives are amortized over their estimated useful lives using the straight-line method.

In-Process Research and Development. The fair value of in-process research and development ("IPR&D") acquired through business combinations is capitalized as an indefinite-lived intangible asset until the completion or

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abandonment of the related research and development activities. When the related research and development is completed, the asset will be assigned a useful life and amortized.

Impairment of Long-Lived Assets. Long-lived assets with finite lives are tested for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. If indicators of impairment are present, the asset is tested for recoverability by comparing the carrying value of the asset to the related estimated undiscounted future cash flows expected to be derived from the asset. If the expected cash flows are less than the carrying value of the asset, then the asset is considered to be impaired and its carrying value is written down to fair value, based on the related estimated discounted future cash flows.

Indefinite-lived intangible assets, including IPR&D, are tested for impairment annually as of October 1 or more frequently if events or changes in circumstances between annual tests indicate that the asset may be impaired. Impairment losses on indefinite-lived intangible assets are recognized based solely on a comparison of the fair value of the asset to its carrying value. Due to the discontinuation of the OPTIC-2L study described in Note 3 below, we considered our indefinite-lived IPR&D asset to be impaired and recorded a $12.0 million impairment charge in research and development expense on the condensed consolidated statements of operations during the three and nine months ended September 30, 2017.

Goodwill. Goodwill is calculated as the difference between the acquisition date fair value of the consideration transferred and the values assigned to the assets acquired and liabilities assumed. Goodwill is not amortized but is tested for impairment at the reporting unit level at least annually as of October 1 or when a triggering event occurs that could indicate a potential impairment by assessing qualitative factors or performing a quantitative analysis in determining whether it is more likely than not that the fair value of net assets are below their carrying amounts. A reporting unit is the same as, or one level below, an operating segment. Our operations are currently comprised of a single, entity wide reporting unit. We completed our most recent impairment assessment as of October 1, 2016 and determined that the carrying value of our reporting unit was not impaired.

Income Taxes. We account for income taxes using the asset and liability approach which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and amounts reportable for income tax purposes. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more-likely-than-not that some portion or all of the deferred tax assets will not be realized.

In addition, we follow the guidance related to accounting for uncertainty in income taxes. This guidance creates a single model to address uncertainty in tax positions and clarifies the accounting for income taxes by prescribing the minimum recognition threshold a tax position is required to meet before it is recognized in the financial statements.

Financing Costs Related to Long-term Debt. Costs associated with obtaining long-term debt are deferred and amortized over the term of the related debt using the effective interest method. Such costs are presented as a direct deduction from the carrying amount of the long-term debt liability, consistent with debt discounts, on the consolidated balance sheets.

Grant Accounting. Grant amounts received from government agencies for operations are deferred and are amortized into income over the service period of the grant. Grant amounts received for purchases of capital assets are deferred and amortized into interest and other income, net over the useful life of the related capital assets. Such amounts are recorded in other liabilities on the condensed consolidated balance sheets.

Net Income (Loss) Per Share. Our basic and diluted net income (loss) per share is calculated by dividing the net income (loss) by the weighted average number of shares of common stock outstanding during all periods presented.

Options to purchase stock, restricted stock units and shares issuable upon the conversion of convertible debt are included in diluted earnings per share calculations, unless the effects are anti-dilutive.

Accumulated Other Comprehensive Income (Loss). Accumulated other comprehensive income (loss) consists of unrealized gains or losses on marketable securities that are classified as available-for-sale, a long-term investment classified as available-for-sale, foreign currency translation gains or losses and defined benefit pension obligations.

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Revenue Recognition. Revenues are recognized when (1) persuasive evidence of an arrangement exists, (2) delivery has occurred or services have been rendered, (3) the price is fixed or determinable and (4) collectability is reasonably assured. Revenues are deferred for fees received before earned or until no further obligations exist. We exercise judgment in determining that collectability is reasonably assured or that services have been delivered in accordance with the arrangement. We assess whether the fee is fixed or determinable based on the payment terms associated with the transaction and whether the sales price is subject to refund or adjustment. We assess collectability based primarily on the customer's payment history and on the creditworthiness of the customer.

Product Revenues

Our product revenues consist of U.S. sales of JAKAFI and European sales of ICLUSIG. Product revenues are recognized once we meet all four revenue recognition criteria described above. In November 2011, we began shipping JAKAFI to our customers in the U.S., which include specialty pharmacies and wholesalers. In June 2016, we acquired the right to and began shipping ICLUSIG to our customers in the European Union and certain other jurisdictions (Note 3), which include retail pharmacies, hospital pharmacies and distributors.

We recognize revenues for product received by our customers net of allowances for customer credits, including estimated rebates, chargebacks, discounts, returns, distribution service fees, patient assistance programs, and government rebates, such as Medicare Part D coverage gap reimbursements in the U.S. Product shipping and handling costs are included in cost of product revenues.

Customer Credits: Our customers are offered various forms of consideration, including allowances, service fees and prompt payment discounts. We expect our customers will earn prompt payment discounts and, therefore, we deduct the full amount of these discounts from total product sales when revenues are recognized. Service fees are also deducted from total product sales as they are earned.

Rebates and Discounts: Allowances for rebates include mandated discounts under the Medicaid Drug Rebate Program in the U.S. and mandated discounts in Europe in markets where government-sponsored healthcare systems are the primary payers for healthcare. Rebates are amounts owed after the final dispensing of the product to a benefit plan participant and are based upon contractual agreements or legal requirements with public sector benefit providers. The accrual for rebates is based on statutory discount rates and expected utilization as well as historical data we have accumulated since product launches. Our estimates for expected utilization of rebates are based on data received from our customers. Rebates are generally invoiced and paid in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's activity, plus an accrual balance for known prior quarters' unpaid rebates. If actual future rebates vary from estimates, we may need to adjust prior period accruals, which would affect revenue in the period of adjustment.

Chargebacks: Chargebacks are discounts that occur when certain contracted customers, which currently consist primarily of group purchasing organizations, Public Health Service institutions, non-profit clinics, and Federal government entities purchasing via the Federal Supply Schedule, purchase directly from our wholesalers. Contracted customers generally purchase the product at a discounted price. The wholesalers, in turn, charges back to us the difference between the price initially paid by the wholesalers and the discounted price paid by the contracted customers. In addition to actual chargebacks received we maintain an accrual for chargebacks based on the estimated contractual discounts on the inventory levels on hand in our distribution channel. If actual future chargebacks vary from these estimates, we may need to adjust prior period accruals, which would affect revenue in the period of adjustment.

Medicare Part D Coverage Gap: Medicare Part D prescription drug benefit mandates manufacturers to fund 50% of the Medicare Part D insurance coverage gap for prescription drugs sold to eligible patients. Our estimates for the

expected Medicare Part D coverage gap are based on historical invoices received and in part from data received from our customers. Funding of the coverage gap is generally invoiced and paid in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's activity, plus an accrual balance for known prior quarters. If actual future funding varies from estimates, we may need to adjust prior period accruals, which would affect revenue in the period of adjustment.

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Co-payment Assistance: Patients who have commercial insurance and meet certain eligibility requirements may receive co-payment assistance. We accrue a liability for co-payment assistance based on actual program participation and estimates of program redemption using data provided by third-party administrators.

Product Royalty Revenues

Royalty revenues on commercial sales for ruxolitinib (marketed as JAKAVI® outside the United States) by Novartis Pharmaceutical International Ltd. ("Novartis") are based on net sales of licensed products in licensed territories as provided by Novartis. Royalty revenues on commercial sales for baricitinib (marketed as OLUMIANT) by Eli Lilly and Company ("Lilly") are based on net sales of licensed products in licensed territories as provided by Lilly. We recognize royalty revenues in the period the sales occur.

Cost of Product Revenues

Cost of product revenues includes all JAKAFI related product costs as well as ICLUSIG related product costs. The ICLUSIG inventories were recorded at fair value less costs to sell in connection with the Acquisition, which resulted in a higher cost of ICLUSIG product revenues over a one year period from the acquisition date. In addition, cost of product revenues include low single digit royalties under our collaboration and license agreement to Novartis on all future sales of JAKAFI in the United States. Subsequent to the Acquisition on June 1, 2016, cost of product revenues also includes the amortization of our licensed intellectual property for ICLUSIG using the straight-line method over the estimated useful life of 12.5 years.

Contract and License Revenues

Under agreements involving multiple deliverables, services and/or rights to use assets that we entered into prior to January 1, 2011, the multiple elements are divided into separate units of accounting when certain criteria are met, including whether the delivered items have stand-alone value to the customer and whether there is objective and reliable evidence of the fair value of the undelivered items. When separate units of accounting exist, consideration is allocated among the separate elements based on their respective fair values. The determination of fair value of each element is based on objective evidence from historical sales of the individual elements by us to other customers. If such evidence of fair value for each undelivered element of the arrangement does not exist, all revenue from the arrangement is deferred until such time that evidence of fair value for each undelivered element does exist or until all elements of the arrangement are delivered. When elements are specifically tied to a separate earnings process, revenue is recognized when the specific performance obligation tied to the element is completed. When revenues for an element are not specifically tied to a separate earnings process, they are recognized ratably over the term of the agreement. We assess whether a substantive milestone exists at the inception of our agreements. For all milestones within our arrangements that are considered substantive, we recognize revenue upon the achievement of the associated milestone. If a milestone is not considered substantive, we would recognize the applicable milestone payment over the remaining period of performance under the arrangement. As of September 30, 2017, all remaining potential milestones under our collaborative arrangements are considered substantive.

On January 1, 2011, updated guidance on the recognition of revenues for agreements with multiple deliverables became effective and applies to any agreements we may enter into on or after January 1, 2011. This updated guidance (i) relates to whether multiple deliverables exist, how the deliverables in a revenue arrangement should be separated and how the consideration should be allocated; (ii) requires companies to allocate revenues in an arrangement using estimated selling prices of deliverables if a vendor does not have vendor-specific objective evidence or third-party evidence of selling price; and (iii) eliminates the use of the residual method and requires companies to allocate revenues using the relative selling price method. During the three and nine months ended September 30, 2017 and 2016, we did not enter into any agreements that are subject to this updated guidance. If we enter into an agreement

with multiple deliverables after January 1, 2011 or amend existing agreements, this updated guidance could have a material effect on our financial statements.

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Our collaborations often include contractual milestones, which typically relate to the achievement of pre-specified development, regulatory and commercialization events. These three categories of milestone events reflect the three stages of the life-cycle of our drugs, which we describe in more detail in the following paragraphs.

The regulatory review and approval process, which includes preclinical testing and clinical trials of each drug candidate, is lengthy, expensive and uncertain. Securing approval by the U.S. Food and Drug Administration (the "FDA") requires the submission of extensive preclinical and clinical data and supporting information to the FDA for each indication to establish a drug candidate's safety and efficacy. The approval process takes many years, requires the expenditure of substantial resources, involves post-marketing surveillance and may involve ongoing requirements for post-marketing studies. Before commencing clinical investigations of a drug candidate in humans, we must submit an Investigational New Drug application ("IND"), which must be reviewed by the FDA.

The steps generally required before a drug may be marketed in the United States include preclinical laboratory tests, animal studies and formulation studies, submission to the FDA of an IND for human clinical testing, performance of adequate and well-controlled clinical trials in three phases, as described below, to establish the safety and efficacy of the drug for each indication, submission of a new drug application ("NDA") or biologics license application ("BLA") to the FDA for review and FDA approval of the NDA or BLA.

Similar requirements exist within foreign regulatory agencies as well. The time required satisfying the FDA requirements or similar requirements of foreign regulatory agencies may vary substantially based on the type, complexity and novelty of the product or the targeted disease.

Preclinical testing includes laboratory evaluation of product pharmacology, drug metabolism, and toxicity, which includes animal studies, to assess potential safety and efficacy as well as product chemistry, stability, formulation, development, and testing. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND. The FDA may raise safety concerns or questions about the conduct of the clinical trials included in the IND, and any of these concerns or questions must be resolved before clinical trials can proceed. We cannot be sure that submission of an IND will result in the FDA allowing clinical trials to commence. Clinical trials involve the administration of the investigational drug or the marketed drug to human subjects under the supervision of qualified investigators and in accordance with good clinical practices regulations covering the protection of human subjects. Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. Phase I usually involves the initial introduction of the investigational drug into healthy volunteers to evaluate its safety, dosage tolerance, absorption, metabolism, distribution and excretion. Phase II usually involves clinical trials in a limited patient population to evaluate dosage tolerance and optimal dosage, identify possible adverse effects and safety risks, and evaluate and gain preliminary evidence of the efficacy of the drug for specific indications. Phase III clinical trials usually further evaluate clinical efficacy and safety by testing the drug in its final form in an expanded patient population, providing statistical evidence of efficacy and safety, and providing an adequate basis for labeling. We cannot guarantee that Phase I, Phase II or Phase III testing will be completed successfully within any specified period of time, if at all. Furthermore, we, the institutional review board for a trial, or the FDA may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

Generally, the milestone events contained in our collaboration agreements coincide with the progression of our drugs from development, to regulatory approval and then to commercialization. The process of successfully discovering a new development candidate, having it approved and successfully commercialized is highly uncertain. As such, the milestone payments we may earn from our partners involve a significant degree of risk to achieve. Therefore, as a drug candidate progresses through the stages of its life-cycle, the value of the drug candidate generally increases.

Research and Development Costs. Our policy is to expense research and development costs as incurred. We often contract with clinical research organizations ("CROs") to facilitate, coordinate and perform agreed upon research and development of a new drug. To ensure that research and development costs are expensed as incurred, we record monthly accruals for clinical trials and preclinical testing costs based on the work performed under the contract.

These CRO contracts typically call for the payment of fees for services at the initiation of the contract and/or upon the achievement of certain clinical trial milestones. In the event that we prepay CRO fees, we record the prepayment

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as a prepaid asset and amortize the asset into research and development expense over the period of time the contracted research and development services are performed. Most professional fees, including project and clinical management, data management, monitoring, and medical writing fees are incurred throughout the contract period. These professional fees are expensed based on their percentage of completion at a particular date. Our CRO contracts generally include pass through fees. Pass through fees include, but are not limited to, regulatory expenses, investigator fees, travel costs, and other miscellaneous costs, including shipping and printing fees. We expense the costs of pass through fees under our CRO contracts as they are incurred, based on the best information available to us at the time. The estimates of the pass through fees incurred are based on the amount of work completed for the clinical trial and are monitored through correspondence with the CROs, internal reviews and a review of contractual terms. The factors utilized to derive the estimates include the number of patients enrolled, duration of the clinical trial, estimated patient attrition, screening rate and length of the dosing regimen. CRO fees incurred to set up the clinical trial are expensed during the setup period.

Under our clinical trial collaboration agreements we may be reimbursed for certain development costs incurred. Such costs are recorded as a reduction of research and development expense in the period in which the related expense is incurred.

Stock Compensation. Share-based payment transactions with employees, which include stock options, restricted stock units (“RSUs”) and performance shares (“PSUs”), are recognized as compensation expense over the requisite service period based on their estimated fair values as well as expected forfeiture rates. The stock compensation process requires significant judgment and the use of estimates, particularly surrounding Black-Scholes assumptions such as stock price volatility over the option term and expected option lives, as well as expected forfeiture rates and the probability of PSUs vesting. The fair value of stock options, which are subject to graded vesting, are recognized as compensation expense over the requisite service period using the accelerated attribution method. The fair value of RSUs that are subject to cliff vesting are recognized as compensation expense over the requisite service period using the straight line attribution method, and the fair value of RSUs that are subject to graded vesting are recognized as compensation expense over the requisite service period using the accelerated attribution method. The fair value of PSUs are recognized as compensation expense beginning at the time in which the performance conditions are deemed probable of achievement, over the remaining requisite service period. We recorded $34.9 million and $99.3 million of stock compensation expense on our condensed consolidated statements of operations for the three and nine months ended September 30, 2017, respectively. We recorded $26.5 million and $68.6 million of stock compensation expense on our condensed consolidated statements of operations for the three and nine months ended September 30, 2016, respectively.

Acquisition-Related Contingent Consideration. Acquisition-related contingent consideration, which consists of our future royalty and certain potential milestone obligations to ARIAD, is recorded on the acquisition date at the estimated fair value of the obligation, in accordance with the acquisition method of accounting. The fair value measurement is based on significant inputs that are unobservable in the market and thus represents a Level 3 measurement. The fair value of the acquisition-related contingent consideration is remeasured each reporting period, with changes in fair value recorded in the condensed consolidated statements of operations.

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”, which will replace numerous requirements in U.S. GAAP, including industry-specific requirements. This guidance provides a five step model to be applied to all contracts with customers, with an underlying principle that an entity will recognize revenue to depict the transfer of goods or services to customers at an amount that the entity expects to be entitled to in exchange for those goods or services. ASC No. 2014-09 requires extensive quantitative and qualitative disclosures covering the nature, amount, timing and

uncertainty of revenue and cash flows arising from customer contracts, including disclosures on significant judgments made when applying the guidance. This guidance is effective for annual reporting periods beginning after December 15, 2017 and interim periods therein. An entity can elect to apply the guidance under one of the following two methods: (i) retrospectively to each prior reporting period presented – referred to as the full retrospective method or (ii) retrospectively with the cumulative effect of initially applying the standard recognized at the date of initial application in retained earnings – referred to as the modified retrospective method.

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We have substantially completed an initial impact assessment of the potential changes from adopting ASU 2014-09. The impact assessment consisted of a review of a representative sample of contracts, discussions with key stakeholders, and a cataloging of potential impacts on our financial statements, accounting policies, financial controls, and operations. We currently do not anticipate a material impact on our revenue recognition practices for product and royalty revenues. We do anticipate that the adoption of ASU 2014-09 will have primarily two impacts on our contract revenues generated by our collaborative research and license agreements:

(i)Changes in the model for distinct licenses of functional intellectual property which may result in a timing difference of revenue recognition. Whereas revenue from these arrangements was previously recognized over a period of time pursuant to revenue recognition guidance that was in place for our arrangements at the time such arrangements commenced, revenue from these arrangements may now be recognized at point in time under the new guidance.

(ii)Assessments of milestone payments, which are linked to events that are in our control, will result in variable consideration that may be recognized at an earlier point in time under the new guidance, when it is probable that the milestone will be achieved without a significant future reversal of cumulative revenue expected.

We have not yet completed our final review of the impact of this guidance including the new disclosure requirements, as we are continuing to evaluate the impacts of adoption and the implementation approach to be used. We plan to adopt the new standard effective January 1, 2018 and are considering adopting using the modified retrospective method. We continue to monitor additional changes, modifications, clarifications or interpretations being undertaken by the FASB, which may impact our current conclusions.

In February 2016, the FASB issued ASU No. 2016-02, “Leases,” that requires lessees to recognize assets and liabilities on the balance sheet for most leases including operating leases. Lessees now classify leases as either finance or operating leases and lessors classify all leases as sales-type, direct financing or operating leases. The statement of operations presentation and expense recognition for lessees for finance leases is similar to that of capital leases under Accounting Standards Codification (“ASC”) 840 with separate interest and amortization expense with higher periodic expense in the earlier periods of a lease. For operating leases, the statement of operations presentation and expense recognition is similar to that of operating leases under ASC 840 with single lease cost recognized on a straight-line basis. This guidance is to be applied using a modified retrospective approach at the beginning of the earliest comparative period presented in the financial statements and is effective for annual periods beginning after December 15, 2018 and interim periods therein. Early adoption is permitted. We are currently analyzing the impact of ASU No. 2016-02 and, at this time, are unable to determine the impact of the new standard on our condensed consolidated financial statements.

In October 2016, the FASB issued ASU No. 2016-16, “Intra-Entity Transfers of Assets Other Than Inventory,” which requires companies to account for the income tax effects of intercompany sales and transfers of assets other than inventory in the period in which the transfer occurs. The new standard is effective for public business entities for annual periods beginning after December 15, 2017 (i.e. 2018 for a calendar-year entity). The guidance will be applied for the annual period beginning January 1, 2018 using a modified retrospective approach with a cumulative catch-up adjustment to opening retained earnings.

We have elected to early adopt ASU No. 2016-16 as of the first quarter of 2017, which requires us to reflect any adjustments as of January 1, 2017, the beginning of the annual period that includes the interim period of adoption. The primary impact of adoption was the recognition of a deferred tax asset of $34.9 million related to the excess of the tax basis over the consolidated book value basis in the intellectual property rights that were licensed from the U.S. parent company to our wholly-owned subsidiary in Switzerland during 2015 and a $2.1 million reversal of long-term prepaid taxes. Under previous guidance, companies were prohibited from recognizing an increase in tax basis and any income taxes incurred as a result of a sale or transfer of assets to companies that are part of a

consolidated reporting entity. Given the full valuation allowance placed on the additional $34.9 million of deferred tax assets, the recognition upon adoption only required a $2.1 million adjustment to our retained earnings as of January 1, 2017 due to the adjustment of the prepaid tax asset.

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In November 2016, the FASB issued ASU No. 2016-18, "Restricted Cash," which requires entities to show the changes in total of cash, cash equivalents, restricted cash and restricted cash equivalents in the statement of cash flows. As a result, entities will no longer present transfers between cash and cash equivalents and restricted cash in the statement of cash flows. When cash, cash equivalents, restricted cash and restricted cash equivalents are presented in more than one line item on the balance sheet, the new guidance requires a reconciliation of the totals in the statement of cash flows to the related captions on the balance sheet. The reconciliation can be presented either on the face of the statement of cash flows or in the notes to the financial statements. The new standard is effective for public business entities for fiscal years beginning after December 15, 2017 and interim periods therein and is to be applied retrospectively. Early adoption is permitted. We are currently analyzing the impact of ASU No. 2016-18 on our condensed consolidated financial statements.

In January 2017, the FASB issued ASU No. 2017-04, "Intangibles–Goodwill and Other," which eliminates the requirement to calculate the implied fair value of goodwill to measure a goodwill impairment charge. Under the new standard, entities will record an impairment charge based on the excess of a reporting unit's carrying amount over its fair value. The new standard is effective for public business entities that are SEC filers for annual or any interim goodwill impairment tests in fiscal years beginning after December 15, 2019. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. The standard is to be applied on a prospective basis. We are currently analyzing the impact of ASU No. 2017-04 on our condensed consolidated financial statements.

In March 2017, the FASB issued ASU No. 2017-07, "Compensation–Retirement Benefits," which requires the presentation of the service cost component of the net periodic benefit cost in the same income statement line as other employee compensation costs arising from services rendered during the period. In addition, only the service cost component will be eligible for capitalization in assets. Disclosure of the line(s) used to present the other components of net periodic benefit cost, if the components are not presented separately in the income statement, is also required. The new standard is effective for public business entities for fiscal years beginning after December 15, 2017 and interim periods therein. The guidance on the presentation of the components of net periodic benefit cost in the income statement is to be applied retrospectively. The guidance limiting the capitalization of net periodic benefit cost in assets to the service cost component is to be applied prospectively. We are currently analyzing the impact of ASU No. 2017-07 on our condensed consolidated financial statements.

In July 2015, the FASB issued ASU No. 2015-11, "Simplifying the Measurement of Inventory," which requires inventory to be measured at the lower of cost and net realizable value rather than at the lower of cost or market value. The new standard is effective for public business entities for fiscal years beginning after December 15, 2016 and interim periods therein. The guidance is to be applied prospectively. We adopted ASU No. 2015-11 as of the first quarter of 2017 and the adoption had no impact on our condensed consolidated financial statements.

3. Business combination

Description of the Transaction

On June 1, 2016, pursuant to the Share Purchase Agreement, we completed the Acquisition, and acquired all of the outstanding shares of ARIAD Pharmaceuticals (Luxembourg) S.à.r.l., since renamed Incyte Biosciences Luxembourg S.à.r.l., the parent company of ARIAD's European subsidiaries responsible for the development and commercialization of ICLUSIG (ponatinib) in the European Union ("EU") and other countries including Switzerland, Norway, Turkey, Israel and Russia (the "Territory") in exchange for an upfront payment of $147.5 million, including customary working capital adjustments (the "Upfront Payment"). ICLUSIG is approved in Europe for the treatment of patients with chronic myeloid leukemia and Philadelphia-positive acute lymphoblastic leukemia who are resistant to or intolerant of certain second generation BCR-ABL inhibitors and all patients who have the T3151 mutation. The acquisition of ARIAD

Pharmaceuticals (Luxembourg) S.à.r.l. included a fully integrated and established pan-European team including medical, sales and marketing personnel. The existing platform and infrastructure acquired is expected to further our strategic plan and accelerate the establishment of our operations in Europe.

In connection with the closing of the Acquisition, we entered into an Amended and Restated Buy-in License Agreement with ARIAD (the "License Agreement"). Under the terms of the License Agreement, we were granted an exclusive license to develop and commercialize ICLUSIG in the Territory. ARIAD is eligible to receive from us tiered

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royalties ranging between 32% and 50% on net sales of ICLUSIG in the Territory. The royalties are subject to reduction for certain events related to exclusivity and, if necessary, any third-party patent rights. In addition, ARIAD is eligible to receive up to $135.0 million in potential future development and regulatory approval milestone payments for ICLUSIG in new oncology indications in the Territory (the "Milestones"), together with additional milestone payments for non-oncology indications, if approved, in the Territory. Under our agreement with ARIAD, we have agreed to fund a portion of the ongoing ICLUSIG clinical studies OPTIC and OPTIC-2L, which are being conducted by ARIAD, by paying up to $7.0 million in both 2016 and 2017 (the "Development Costs"). During the quarter ended September 30, 2017, ARIAD discontinued the OPTIC-2L clinical study.

The terms of the License Agreement also include a limited option for a potential future acquirer of ARIAD to purchase the European development and commercialization rights to ICLUSIG from us (the "Buy-Back Provision"). We concluded the Buy-Back Provision was not a derivative as it did not provide for explicit or implicit net settlement, cannot be readily settled net by a means outside of the contract, and does not provide for delivery of an asset that puts the recipient in a position that is not substantially different from net settlement. We also considered the probability of a potential future buyer exercising the Buy-Back Provision to be near zero and have concluded that any fair value assigned to this provision was de minimis. Takeda Pharmaceutical Company Limited acquired ARIAD in February 2017 but did not exercise the Buy-Back Provision, and the Buy-Back Provision lapsed.

Unless terminated earlier in accordance with its provisions, our obligations to pay full royalties under the License Agreement will continue to be in effect on a country-by-country basis until the latest to occur of (1) the expiration date of the composition patent in the relevant country, (2) the expiration of any regulatory marketing exclusivity period or other statutory designation that provides similar exclusivity for the commercialization of ICLUSIG in such country and (3) the seventh anniversary of the first commercial sale of ICLUSIG in such country. We will be obligated to pay royalties at a reduced rate for a specified period of time following such full royalty term. The License Agreement may be terminated in its entirety by us for convenience on 12 months' notice after the third anniversary of the effective date of the License Agreement. The License Agreement may also be terminated by either party under certain other circumstances, including material breach, as set forth in the License Agreement.

Fair Value of Consideration Transferred

The preliminary fair value of consideration transferred totaled $440.5 million, which consisted of $147.5 million in cash pursuant to the Share Purchase Agreement, including net working capital adjustments, and $293.0 million of contingent consideration related to the License Agreement. Contingent consideration includes the future payments that we may pay to ARIAD for our royalty obligations on future net sales of ICLUSIG, as well as for any future potential milestone payments related to new oncology or non-oncology indications for ICLUSIG.

The preliminary fair value of contingent consideration was determined using an income approach based on estimated ICLUSIG revenues in the Territory for both the approved third line treatment, as well as the second line treatment that was under development and was therefore contingent on future clinical results and European Medicines Agency ("EMA") approval. The probability of technical success ("PTS") of the second line indication was estimated at 25% based on the early stage of development and competitive market landscape, and the estimated future cash flows for the second line indication were probability weighted accordingly. The total projected cash flows of the third line and second line indications were estimated over 18 years, and discounted to present value using a discount rate of 10%. In addition, based on the believed limited effectiveness of ICLUSIG beyond the existing oncology indications, the fact that no development is currently ongoing for any new oncology or any non-oncology indications, and the lack of intention by us, ARIAD, or another market participant, to develop ICLUSIG in additional oncology or non-oncology indications, the fair value of any cash flows for any new oncology or non-oncology indication was determined to be nil. The present value of the contingent consideration was $293.0 million as of the Acquisition date.

Assets Acquired and Liabilities Assumed

The Acquisition has been accounted for as a business combination under the acquisition method of accounting. The following table summarizes the final fair values of the assets acquired and liabilities assumed as of the acquisition date.

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(in thousands)	Acquisition Fair Values
Current assets	$ 21,363
Property and equipment	850
Restricted cash	432
Intangible assets(a)	283,000
Total identifiable assets	305,645
Current liabilities	(15,538)
Other long term liabilities	(5,226)
Total liabilities assumed	(20,764)
Goodwill(b)	155,593
Total fair value of consideration transferred	$ 440,474

(a)As of the effective date of the Acquisition, identifiable intangible assets are required to be measured at fair value. The fair value measurement is based on significant inputs that are unobservable in the market and thus represents a Level 3 measurement. We used an income approach to estimate the preliminary fair value of the intangibles which includes licensed intellectual property and IPR&D. The assumptions used to estimate the cash flows of the licensed intellectual property included a discount rate of 15%, estimated gross margins of 98%, income tax rates ranging from 7.8% in periods in which we have established tax holidays to 13.8% thereafter, and operating expenses consisting of direct costs based on the anticipated level of revenues as well as the $7.0 million of research and development cost sharing payments we owe in 2016 and 2017. The assumptions used to estimate the cash flows of the IPR&D (which related to the potential approval of ICLUSIG as a second line treatment and, as described in Note 8 below, has subsequently been written off) included a PTS of 25%, discount rate of 16%, estimated gross margins of 98%, income tax rates ranging from 7.8% in periods in which we have established tax holidays to 13.8% thereafter, and operating expenses consisting of direct costs based on the anticipated level of revenues as well as probability weighted milestone payments estimated for 2020 related to the clinical results and potential approval of ICLUSIG as a second line treatment. The licensed intellectual property has a weighted-average useful life of approximately 12.5 years and will be amortized using the straight-line method. Amortization expense of the licensed intellectual property is recorded in cost of product revenues on the condensed consolidated statement of operations. The IPR&D was considered an indefinite-lived intangible until the completion or abandonment of the related research and development activities.

(b)Goodwill is calculated as the difference between the acquisition date fair value of the consideration transferred and the fair values of the assets acquired and liabilities assumed. The Goodwill is related to the existing platform, infrastructure, and workforce which is expected to generate synergies and further our strategic plan in Europe. Goodwill is not amortized and none of the goodwill is expected to be deductible for tax purposes.

Pro Forma Impact of Business Combination

The following unaudited pro forma information presents condensed consolidated results of operations for the three and nine months ended September 30, 2016, as if the Acquisition had occurred as of January 1, 2015 (in thousands).

	For the Three Months Ended September 30, 2016	For the Nine Months Ended September 30, 2016
Pro forma revenues	$ 269,469	$ 821,743

Pro forma net income	$ 36,877	$ 91,248

The unaudited pro forma condensed consolidated results of operations were prepared using the acquisition method of accounting and are based on the historical financial information of our company and the acquired business which has been adjusted for events that are (1) directly attributable to the Acquisition, (2) factually supportable, and (3) expected to have continuing impact on the combined results. The unaudited pro forma information reflects primarily the following adjustments:

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- To record amortization expense related to fair value adjustments recorded on the acquired definite lived intangibles;
- To eliminate ARIAD Europe's interest expense on the intercompany loan in accordance with the terms of the Acquisition;
- To remove balances attributable to the ARIAD Australia entity which are not material. This entity was previously consolidated by ARIAD Europe; however it was not included in the Acquisition; and
- To remove the recognition of revenue relating to distribution agreements in historic periods for those arrangements in which we have no continuing performance obligation and, therefore, the fair value of the assumed deferred revenue balance was zero.

The unaudited pro forma information is not necessarily indicative of the results that would have been obtained if the Acquisition had occurred as of the beginning of the period presented or that may occur in the future, and does not reflect future synergies, integration costs, or other such costs or savings.

4. Fair value of financial instruments

FASB accounting guidance defines fair value as the price that would be received to sell an asset or paid to transfer a liability ("the exit price") in an orderly transaction between market participants at the measurement date. The standard outlines a valuation framework and creates a fair value hierarchy in order to increase the consistency and comparability of fair value measurements and the related disclosures. In determining fair value we use quoted prices and observable inputs. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of us. The fair value hierarchy is broken down into three levels based on the source of inputs as follows:

Level 1—Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities.

Level 2—Valuations based on observable inputs and quoted prices in active markets for similar assets and liabilities.

Level 3—Valuations based on inputs that are unobservable and models that are significant to the overall fair value measurement.

Recurring Fair Value Measurements

Our marketable securities consist of investments in corporate debt securities and U.S. government securities that are classified as available-for-sale.

At September 30, 2017 and December 31, 2016, our Level 2 corporate debt securities were valued using readily available pricing sources which utilize market observable inputs, including the current interest rate and other characteristics for similar types of investments. Our long term investments classified as Level 1 were valued using the unadjusted closing stock price on The NASDAQ Stock Market.

Our policy is to recognize transfers into and transfers out of fair value hierarchy levels as of the end of the reporting period. During the three months ended September 30, 2017, we transferred a long term investment with a carrying value of $78.3 million from Level 2 to Level 1 due to the lapse of the marketability restrictions. The investment is now valued using the unadjusted closing stock price on The NASDAQ Stock Market. There were no transfers out of Level 1 to Level 2 during the period.

The following fair value hierarchy table presents information about each major category of our financial assets measured at fair value on a recurring basis as of September 30, 2017 (in thousands):

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	Fair Value Measurement at Reporting Date Using:			
	Quoted Prices in Active Markets for Identical Assets	Significant Other Observable Inputs	Significant Unobservable Inputs	
	(Level 1)	(Level 2)	(Level 3)	Balance as of September 30, 2017
Cash and cash equivalents	$ 1,128,046	$ —	$ —	$ 1,128,046
Debt securities (corporate and government)	—	153,343	—	153,343
Long term investments (Note 9)	169,020	—	—	169,020
Total assets	$ 1,297,066	$ 153,343	$ —	$ 1,450,409

The following fair value hierarchy table presents information about each major category of our financial liabilities measured at fair value on a recurring basis as of September 30, 2017 (in thousands):

	Fair Value Measurement at Reporting Date Using:			
	Quoted Prices in Active Markets for Identical Assets	Significant Other Observable Inputs	Significant Unobservable Inputs	
	(Level 1)	(Level 2)	(Level 3)	Balance as of September 30, 2017
Contingent consideration (Note 3)	$ —	$ —	$ 284,000	$ 284,000
Total liabilities	$ —	$ —	$ 284,000	$ 284,000

The following is a rollforward of our Level 3 liabilities (in thousands):

	Level 3
Balance at January 1, 2017	$ 301,000
Contingent consideration earned during the period but not yet paid	(5,657)
Payments made during the period	(9,429)
Change in fair value of contingent consideration	(1,914)
Balance at September 30, 2017	$ 284,000

The fair value of the contingent consideration was determined using an income approach based on estimated ICLUSIG revenues in the Territory for both the approved third line treatment, as well as the second line treatment that was under development until discontinued in the third quarter of 2017. The fair value of the contingent consideration is remeasured each reporting period, with changes in fair value recorded in the condensed consolidated statements of operations. The change in fair value of the contingent consideration during the three and nine months ended September 30, 2017 is due to the passage of time and a benefit of $24.0 million recorded during the third quarter related to the lack of expected future sales royalties payable due to the discontinued OPTIC-2L clinical trial.

We make payments to ARIAD quarterly based on the royalties or any additional milestone payments earned in the previous quarter. During the three months ended September 30, 2017, contingent consideration earned but not yet paid was $5.7 million and we paid ARIAD $5.1 million for royalties earned in the second quarter of 2017 that were included in accrued and other current liabilities at June 30, 2017.

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The following fair value hierarchy table presents information about each major category of our financial assets measured at fair value on a recurring basis as of December 31, 2016 (in thousands):

	Fair Value Measurement at Reporting Date Using:			
	Quoted Prices in Active Markets for Identical Assets	Significant Other Observable Inputs	Significant Unobservable Inputs	Balance as of December 31, 2016
	(Level 1)	(Level 2)	(Level 3)	
Cash and cash equivalents	$ 652,343	$ —	$ —	$ 652,343
Debt securities (corporate and government)	—	156,203	—	156,203
Long term investment (Note 9)	31,987	—	—	31,987
Total assets	$ 684,330	$ 156,203	$ —	$ 840,533

The following fair value hierarchy table presents information about each major category of our financial liabilities measured at fair value on a recurring basis as of December 31, 2016 (in thousands):

	Fair Value Measurement at Reporting Date Using:			
	Quoted Prices in Active Markets for Identical Assets	Significant Other Observable Inputs	Significant Unobservable Inputs	Balance as of December 31, 2016
	(Level 1)	(Level 2)	(Level 3)	
Contingent consideration (Note 3)	$ —	$ —	$ 301,000	$ 301,000
Total liabilities	$ —	$ —	$ 301,000	$ 301,000

The following is a summary of our marketable security portfolio as of September 30, 2017 and December 31, 2016, respectively.

	Amortized Cost	Net Unrealized Gains	Net Unrealized Losses	Estimated Fair Value
	(in thousands)			
September 30, 2017				
Debt securities (corporate and government)	$ 153,650	$ —	$ (307)	$ 153,343
December 31, 2016				
Debt securities (corporate and government)	$ 156,330	$ —	$ (127)	$ 156,203

Our debt securities generally have contractual maturity dates of between 12 to 18 months.

5. Concentration of credit risk

In December 2009, we entered into a license, development and commercialization agreement with Lilly. In November 2009, we entered into a collaboration and license agreement with Novartis. The concentration of credit risk related to our collaborative partners is as follows:

	Percentage of Total Contract Revenues for the Three Months Ended September 30,				Percentage of Total Contract Revenues for the Nine Months Ended September 30,			
	2017		2016		2017		2016	
Collaboration Partner A	—	%	—	%	24	%	7	%
Collaboration Partner B	100	%	100	%	76	%	93	%

Collaboration Partner A and Collaboration Partner B comprised in the aggregate 23% and 23% of the accounts receivable balance as of September 30, 2017 and December 31, 2016, respectively.

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In November 2011, we began commercialization and distribution of JAKAFI to a number of customers. Our product revenues are concentrated in a number of these customers. The concentration of credit risk related to our JAKAFI product revenues is as follows:

	Percentage of Total Net Product Revenues for the Three Months Ended September 30,				Percentage of Total Net Product Revenues for the Nine Months Ended September 30,			
	2017		2016		2017		2016	
Customer A	24	%	25	%	25	%	26	%
Customer B	16	%	19	%	16	%	18	%
Customer C	14	%	13	%	13	%	13	%
Customer D	8	%	8	%	8	%	8	%

We are exposed to risks associated with extending credit to customers related to the sale of products. Customer A, Customer B, Customer C and Customer D comprised in the aggregate 44% and 41% of the accounts receivable balance as of September 30, 2017 and December 31, 2016, respectively.

The concentration of credit risk relating to ICLUSIG product revenues or accounts receivable is not significant.

6. Inventory

Our inventory balance consists of the following:

	September 30, 2017	December 31, 2016
	(in thousands)	
Raw materials	$ 109	$ 109
Work-in-process	11,188	15,084
Finished goods	3,261	4,106
	14,558	19,299
Inventories-current	3,261	4,106
Inventories-non-current	$ 11,297	$ 15,193

Inventories, stated at the lower of cost and net realizable value, consist of raw materials, work in process and finished goods. The ICLUSIG inventories acquired on June 1, 2016 totaling $4.0 million were recorded at fair value less costs to sell, and therefore, resulted in a higher cost of ICLUSIG revenues over a one year period from the acquisition date. At September 30, 2017, $3.3 million of inventory was classified as current on the condensed consolidated balance sheet as we expect this inventory to be consumed for commercial use within the next twelve months. At September 30, 2017, $11.3 million of inventory was classified as non-current on the condensed consolidated balance sheets as we did not expect this inventory to be consumed for commercial use within the next twelve months. We obtain some inventory components from a limited number of suppliers due to technology, availability, price, quality or other considerations. The loss of a supplier, the deterioration of our relationship with a supplier, or any unilateral violation of the contractual terms under which we are supplied components by a supplier could adversely affect our total revenues and gross margins.

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7. Property and equipment, net

Property and equipment, net consists of the following:

	September 30, 2017	December 31, 2016
	(in thousands)	
Office equipment	$ 10,554	$ 9,243
Laboratory equipment	44,299	37,203
Computer equipment	47,522	38,184
Land	5,350	4,125
Building and leasehold improvements	208,171	130,734
	315,896	219,489
Less accumulated depreciation and amortization	(69,071)	(51,810)
Property and equipment, net	$ 246,825	$ 167,679

In September 2016, we entered into two agreements to purchase two buildings at 1701 Augustine Cut-off in Wilmington, Delaware. The purchase closed in March 2017 for a total purchase price of approximately $8.1 million, consisting of $1.2 million of land and $6.9 million of buildings and leasehold improvements, which we estimated using the assistance of a third party valuation specialist.

8. Intangible assets and goodwill

Intangible Assets, Net

The components of intangible assets as of September 30, 2017 were as follows (in thousands, except for useful life):

	Weighted-Average Useful Lives (Years)	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Finite-lived intangible assets:				
Licensed IP(1)	12.5	$ 271,000	$ 28,715	$ 242,285
Indefinite-lived intangible assets:				
Acquired IPR&D(1)	N/A	—	—	—
		$ 271,000	$ 28,715	$ 242,285

(1) We acquired certain intangible assets as part of the Acquisition, as described further in Note 3. During the three months ended September 30, 2017, we wrote-off the acquired IPR&D asset of $12.0 million due to the discontinuation of the OPTIC-2L study. The write-off of the IPR&D asset was recorded in research and development expense on the condensed consolidated statements of operations.

Estimated aggregate amortization expense based on the current carrying value of amortizable intangible assets is as follows (in thousands):

Remainder of 2017	2018	2019	2020	2021	Thereafter

Amortization expense	$ 5,384	$ 21,536	$ 21,536	$ 21,536	$ 21,536	$ 150,757

Goodwill

There were no changes to the carrying amount of goodwill for the nine months ended September 30, 2017.

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9. License agreements

Novartis

In November 2009, we entered into a Collaboration and License Agreement with Novartis. Under the terms of the agreement, Novartis received exclusive development and commercialization rights outside of the United States to our JAK inhibitor ruxolitinib and certain back-up compounds for hematologic and oncology indications, including all hematological malignancies, solid tumors and myeloproliferative diseases. We retained exclusive development and commercialization rights to JAKAFI (ruxolitinib) in the United States and in certain other indications. Novartis also received worldwide exclusive development and commercialization rights to our c-MET inhibitor compound capmatinib and certain back-up compounds in all indications. We retained options to co-develop and to co-promote capmatinib in the United States.

Under this agreement, we received an upfront payment and immediate milestone payment totaling $210.0 million and were initially eligible to receive up to $1.2 billion in milestone payments across multiple indications upon the achievement of pre-specified events, including up to $174.0 million for the achievement of development milestones, up to $495.0 million for the achievement of regulatory milestones and up to $500.0 million for the achievement of commercialization milestones. In April 2016, we amended this agreement to provide that Novartis has exclusive research, development and commercialization rights outside of the United States to ruxolitinib (excluding topical formulations) in the graft-versus-host-disease ("GVHD") field. We became eligible to receive up to $75.0 million of additional potential development and regulatory milestones relating to GVHD. Exclusive of the upfront payment of $150.0 million received in 2009 and the immediate milestone of $60.0 million earned in 2010, we have recognized and received in the aggregate $132.0 million for the achievement of development milestones and $215.0 million for the achievement of regulatory milestones and $20.0 million for the achievement of sales milestones through September 30, 2017.

During the nine months ended September 30, 2017, under this agreement, we recognized a $25.0 million development milestone payment based on the formal initiation by Novartis of a Phase III clinical trial evaluating ruxolitinib in GVHD. In 2016, we recognized a $5.0 million payment in exchange for the development and commercialization rights to ruxolitinib in GVHD outside of the United States and a $40.0 million regulatory milestone for the reimbursement of JAKAVI in Europe for the treatment of patients with polycythemia vera. In 2015, we recognized a $5.0 million development milestone based on the formal initiation by Novartis of a Phase II clinical trial evaluating capmatinib for a third indication, a $25.0 million regulatory milestone triggered by the Committee for Medicinal Products for Human Use of the European Medicines Agency adopting a positive opinion for JAKAVI (ruxolitinib) for the treatment of adult patients with polycythemia vera who are resistant to or intolerant of hydroxyurea, a $15.0 million regulatory milestone for the approval of JAKAVI in Japan for the treatment of patients with polycythemia vera, and a $20.0 million sales milestone for Novartis achieving annual net sales of a JAK licensed product of $300.0 million. In 2014, we recognized a $60.0 million regulatory milestone related to reimbursement of JAKAVI in Europe, a $25.0 million regulatory milestone for the approval of JAKAVI in Japan for the treatment of patients with myelofibrosis and a $7.0 million development milestone based on the formal initiation by Novartis of a Phase II clinical trial evaluating capmatinib in non-small cell lung cancer. In 2013, we recognized a $25.0 million development milestone based on the formal initiation by Novartis of a Phase II clinical trial evaluating capmatinib. In 2012, we recognized a $40.0 million regulatory milestone payment for the achievement of a predefined milestone for the European Union regulatory approval of JAKAVI. In 2011, we recognized a $15.0 million development milestone for the achievement of a predefined milestone in the Phase I dose-escalation trial for capmatinib in patients with solid tumors and a $10.0 million regulatory milestone for the approval of JAKAFI in the United States. In 2010, we recognized $50.0 million in development milestones for the initiation of the global phase III trial, RESPONSE, in patients with polycythemia vera. We determined that each of these milestones were substantive as their achievement required substantive efforts by us and was at risk until the milestones were ultimately achieved.

We also are eligible to receive tiered, double-digit royalties ranging from the upper-teens to the mid-twenties on future JAKAVI net sales outside of the United States, and tiered, worldwide royalties on future capmatinib net sales that range from 12% to 14%. Since the achievement of the $60.0 million regulatory milestone related to reimbursement of JAKAVI in Europe in September 2014, we are obligated to pay to Novartis tiered royalties in the low single digits on future JAKAFI net sales within the United States. During the three and nine months ended September 30, 2017, such royalties payable to Novartis on net sales within the United States totaled $14.9 million and $35.7 million, respectively,

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and are reflected in cost of product revenues on the condensed consolidated statements of operations. During the three and nine months ended September 30, 2016, such royalties payable to Novartis on net sales within the United States totaled $11.0 million and $25.1 million, respectively, and are reflected in cost of product revenues on the condensed consolidated statements of operations. Each company is responsible for costs relating to the development and commercialization of ruxolitinib in its respective territories, with costs of collaborative studies shared equally. Novartis is also responsible for all costs relating to the development and commercialization of capmatinib.

The Novartis agreement will continue on a program-by-program basis until Novartis has no royalty payment obligations with respect to such program or, if earlier, the termination of the agreement or any program in accordance with the terms of the agreement. Royalties are payable by Novartis on a product-by-product and country-by-country basis until the latest to occur of (1) the expiration of the last valid claim of the licensed patent rights covering the licensed product in the relevant country, (2) the expiration of regulatory exclusivity for the licensed product in such country and (3) a specified period from first commercial sale in such country of the licensed product by Novartis or its affiliates or sublicensees. The agreement may be terminated in its entirety or on a program-by-program basis by Novartis for convenience. The agreement may also be terminated by either party under certain other circumstances, including material breach.

We determined that there were two deliverables under the agreement: (i) the ex-U.S. license for ruxolitinib and (ii) our obligations in connection with our participation on the joint development committee for myelofibrosis and polycythemia vera/essential thrombocythemia. We concluded that these deliverables should be accounted for as a single unit of accounting and the $150.0 million upfront payment received in December 2009 and the immediate $60.0 million milestone payment received in January 2010 should be recognized on a straight line basis through December 2013, when we estimated we would complete our obligations in connection with our participation on the joint development committee for myelofibrosis and polycythemia vera, our estimated performance period under the agreement. We completed this substantive performance obligation related to this arrangement in December 2013.

At December 31, 2009, we recorded $10.9 million of reimbursable costs incurred prior to the effective date of the agreement as deferred revenue on the consolidated balance sheet. These costs were recognized on a straight line basis through December 2013 consistent with the aforementioned upfront and milestone payments. Future reimbursable costs incurred after the effective date of the agreement with Novartis are recorded net against the related research and development expenses. At September 30, 2017 and December 31, 2016, $1.0 million and $0.6 million, respectively, of reimbursable costs were included in accounts receivable on the condensed consolidated balance sheets. Research and development expenses for the three and nine months ended September 30, 2017 were net of $0.4 million and $1.9 million, respectively, of costs reimbursed by Novartis. Research and development expenses for the three and nine months ended September 30, 2016 were net of $0.3 million and $0.7 million, respectively, of costs reimbursed by Novartis.

Contract revenue under the Novartis agreement was $0.0 million and $25.0 million for the three and nine months ended September 30, 2017, respectively. Contract revenue under the Novartis agreement was $0.0 million and $5.0 million for the three and nine months ended September 30, 2016. Product royalty revenue related to Novartis net sales of JAKAVI outside of the United States was $41.3 million and $104.0 million for the three and nine months ended September 30, 2017, respectively. Product royalty revenue related to Novartis net sales of JAKAVI outside of the United States was $29.6 million and $77.5 million for the three and nine months ended September 30, 2016, respectively. At September 30, 2017 and December 31, 2016, $41.3 million and $33.3 million, respectively, of product royalties were included in accounts receivable on the condensed consolidated balance sheets.

Lilly - Baricitinib

In December 2009, we entered into a License, Development and Commercialization Agreement with Lilly. Under the terms of the agreement, Lilly received exclusive worldwide development and commercialization rights to our JAK inhibitor baricitinib, and certain back-up compounds for inflammatory and autoimmune diseases. We received an upfront payment of $90.0 million, and were initially eligible to receive up to $665.0 million in substantive milestone payments across multiple indications upon the achievement of pre-specified events, including up to $150.0 million for the achievement of development milestones, up to $365.0 million for the achievement of regulatory milestones and up to $150.0 million for the achievement of commercialization milestones. Exclusive of the upfront payment of $90.0 million

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received in 2009, we have recognized and received in the aggregate $99.0 million for the achievement of development milestones and $135.0 million for the achievement of regulatory milestones through September 30, 2017.

In April 2017, we and Lilly announced that the FDA had issued a complete response letter for the New Drug Application of baricitinib as a once-daily oral medication for the treatment of moderate-to-severe rheumatoid arthritis. The letter indicates that the FDA is unable to approve the application in its current form. Specifically, the FDA indicated that additional clinical data are needed to determine the most appropriate doses. The FDA also stated that additional data are necessary to further characterize safety concerns across treatment arms. In August 2017, we and Lilly announced that a resubmission of the NDA for baricitinib is now expected before the end of January 2018. The resubmission package will include new safety and efficacy data. The companies anticipate the FDA will classify the application as a Class II resubmission, which would start a new six-month review cycle.

During the nine months ended September 30, 2017, under this agreement, we recognized a $15.0 million regulatory milestone payment for the approval of baricitinib for the treatment of rheumatoid arthritis by Japan's Ministry of Health, Labor and Welfare and a $65.0 million regulatory milestone payment for the approval of baricitinib for the treatment of moderate-to-severe rheumatoid arthritis in adult patients by the European Commission. In 2016, we recognized a $35.0 million regulatory milestone for the submission of an NDA to the FDA for the approval of oral once-daily baricitinib for the treatment of moderate-to-severe rheumatoid arthritis and a $20.0 million regulatory milestone for the submission of a Marketing Authorization Application to the European Medicines Agency for the approval of oral once-daily baricitinib for the treatment of moderate-to-severe rheumatoid arthritis. In 2012, we recognized a $50.0 million development milestone for the initiation of the rheumatoid arthritis Phase III program for baricitinib. In 2010, we recognized a $30.0 million development milestone based upon the initial three month data in the Phase IIa clinical trial of baricitinib for the treatment of rheumatoid arthritis and a $19.0 million development milestone for the Phase IIb clinical trial initiation of baricitinib for the treatment of rheumatoid arthritis. We determined that each of these milestones were substantive as their achievement required substantive efforts by us and was at risk until the milestones were ultimately achieved. In July 2010, we elected to co-develop baricitinib with Lilly in rheumatoid arthritis and we are responsible for funding 30% of the associated future global development costs for this indication from the initiation of the Phase IIb trial through regulatory approval, including post-launch studies required by a regulatory authority. In January 2017, we exercised our co-development option in psoriatic arthritis to fund 30% of future global development costs through regulatory approval, including post-launch studies required by a regulatory authority. We also exercised our co-development options in both atopic dermatitis and axial spondyloarthritis, should Lilly decide to progress into a pivotal program in these indications.

We retained options to co-develop our JAK1/JAK2 inhibitors with Lilly on a compound-by-compound and indication-by-indication basis. Lilly is responsible for all costs relating to the development and commercialization of the compounds unless we elect to co-develop any compounds or indications. If we elect to co-develop any compounds and/or indications, we would be responsible for funding 30% of the associated future global development costs from the initiation of a Phase IIb trial through regulatory approval, including post-launch studies required by a regulatory authority. We would receive an incremental royalty rate increase across all tiers resulting in effective royalty rates ranging up to the high twenties on potential future global net sales for compounds and/or indications that we elect to co-develop. For indications that we elect not to co develop, we would receive tiered, double digit royalty payments on future global net sales with rates ranging up to 20% if the product is successfully commercialized. We previously had retained an option to co-promote products in the United States but, in March 2016, we waived our co-promotion option as part of an amendment to the agreement. In February 2017, the European Commission approved baricitinib, which is marketed as OLUMIANT, for the treatment of moderate-to-severe rheumatoid arthritis in adult patients.

Research and development expenses recorded under the Lilly agreement representing 30% of the global development costs for baricitinib for the treatment of rheumatoid arthritis, psoriatic arthritis and atopic dermatitis were $9.1 million and $27.2 million for the three and nine months ended September 30, 2017, respectively. Research and development

expenses recorded under the Lilly agreement representing 30% of the global development costs for baricitinib for the treatment of rheumatoid arthritis were $10.6 million and $21.0 million for the three and nine months ended September 30, 2016, respectively. We have retained certain mechanisms to give us cost protection as baricitinib advances in clinical development. We can defer our portion of co-development study costs by indication if they exceed a predetermined level. This deferment would be credited against future milestones or royalties and we would still be eligible

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for the full incremental royalties related to the co-development option. In addition, even if we have started co-development funding for any indication, we can at any time opt out and stop future co-development cost sharing. If we elect to do this we would still be eligible for our base royalties plus an incremental pro-rated royalty commensurate with our contribution to the total co-development cost for those indications for which we co-funded. The Lilly agreement will continue until Lilly no longer has any royalty payment obligations or, if earlier, the termination of the agreement in accordance with its terms. Royalties are payable by Lilly on a product-by-product and country-by-country basis until the latest to occur of (1) the expiration of the last valid claim of the licensed patent rights covering the licensed product in the relevant country, (2) the expiration of regulatory exclusivity for the licensed product in such country and (3) a specified period from first commercial sale in such country of the licensed product by Lilly or its affiliates or sublicensees. The agreement may be terminated by Lilly for convenience, and may also be terminated under certain other circumstances, including material breach.

We determined that there were two deliverables under the agreement: (i) the worldwide license and (ii) our obligations in connection with a co-development option. We concluded that these deliverables should be accounted for as a single unit of accounting and the $90.0 million upfront payment should be recognized on a straight line basis as revenue through December 2016, our estimated performance period under the agreement. We completed our substantive performance obligation related to this arrangement in December 2016.

Contract revenue under the Lilly agreement was $15.0 million and $80.0 million for the three and nine months ended September 30, 2017, respectively. Contract revenue under the Lilly agreement was $3.2 million and $64.6 million for the three and nine months ended September 30, 2016, respectively. Product royalty revenue related to Lilly global net sales of OLUMIANT was $3.2 million and $4.5 million for the three and nine months ended September 30, 2017, respectively. At September 30, 2017, $3.2 million of product royalties were included in accounts receivable on the condensed consolidated balance sheet.

Lilly - Ruxolitinib

In March 2016, we entered into an amendment to the agreement with Lilly that amended the non-compete provision of the agreement to allow us to engage in the development and commercialization of ruxolitinib in the GVHD field. We paid Lilly an upfront payment of $35.0 million and Lilly is eligible to receive up to $40.0 million in additional regulatory milestone payments relating to ruxolitinib in the GVHD field. During the nine months ended September 30, 2016, the $35.0 million upfront payment was recorded in research and development expense on the condensed consolidated statements of operations.

Agenus

In January 2015, we entered into a License, Development and Commercialization Agreement with Agenus Inc. and its wholly-owned subsidiary, 4-Antibody AG, (now known as Agenus Switzerland Inc.), which we collectively refer to as Agenus. Under this agreement, the parties have agreed to collaborate on the discovery of novel immuno-therapeutics using Agenus' antibody discovery platforms. The agreement became effective on February 18, 2015, upon the expiration of the waiting period under the Hart Scott Rodino Antitrust Improvements Act of 1976. In February 2017, we and Agenus amended this agreement (the "Amended Agreement").

Under the terms of the Amended Agreement, we received exclusive worldwide development and commercialization rights to four checkpoint modulators directed against GITR, OX40, LAG-3 and TIM-3. In addition to the initial four program targets, we and Agenus have the option to jointly nominate and pursue additional targets within the framework of the collaboration, and in November 2015, three more targets were added. Targets may be designated profit-share programs, where all costs and profits are shared equally by us and Agenus, or royalty-bearing programs, where we are responsible for all costs associated with discovery, preclinical, clinical development and

commercialization activities. The programs relating to GITR and OX40 and two of the undisclosed targets were profit-share programs until February 2017, while the other targets currently under collaboration are royalty-bearing programs. The Amended Agreement converted the programs relating to GITR and OX40 to royalty-bearing programs and removed from the collaboration the profit-share programs relating to the two undisclosed targets, with one reverting to us and one reverting to Agenus. Should any of those removed programs be successfully developed by a party, the other party will be eligible

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to receive the same milestone payments as the royalty-bearing programs and royalties at a 15% rate on global net sales. There are currently no profit-share programs. For each royalty-bearing product other than GITR and OX40, Agenus will be eligible to receive tiered royalties on global net sales ranging from 6% to 12%. For GITR and OX40, Agenus will be eligible to receive 15% royalties on global net sales.

Under the Amended Agreement, we paid Agenus $20.0 million in accelerated milestones relating to the clinical development of the GITR and OX40 programs, which is recorded in research and development expense on the condensed consolidated statement of operations during the nine months ended September 30, 2017. Agenus is eligible to receive up to an additional $510.0 million in future contingent development, regulatory and commercialization milestones across all programs in the collaboration. The agreement may be terminated by us for convenience upon 12 months' notice and may also be terminated under certain other circumstances, including material breach.

In connection with the Amended Agreement, we also agreed to purchase 10.0 million shares of Agenus Inc. common stock for an aggregate purchase price of $60.0 million in cash, or $6.00 per share. We completed the purchase of the shares on February 14, 2017, when the closing price on The NASDAQ Stock Market for Agenus Inc. shares was $4.40 per share. The shares we acquired were not registered under the Securities Act of 1933 on the purchase date and are subject to certain security specific restrictions for a period of time, and accordingly, we estimated a discount for lack of marketability on the shares on the issuance date of $4.5 million, which resulted in a total fair value of the shares on the issuance date of $39.5 million. Therefore, of the total consideration paid of $60.0 million, $39.5 million was allocated to our stock purchase in Agenus Inc. and was recorded within long term investments on the condensed consolidated balance sheets and $20.5 million was allocated to research and development expense on the condensed consolidated statement of operations during the nine months ended September 30, 2017.

We have concluded Agenus Inc. is not a VIE because it has sufficient equity to finance its activities without additional subordinated financial support and its at-risk equity holders have the characteristics of a controlling financial interest. From the date of our initial stock purchase in February 2015 and up to the date of our second stock purchase in February 2017, we owned between 9% and 11% of the outstanding shares of Agenus Inc. common stock. As a result of our February 2017 stock purchase, we owned approximately 18% of the outstanding shares of Agenus Inc. common stock as of September 30, 2017. We concluded that we have the ability to exercise significant influence, but not control, over Agenus Inc. based primarily on our ownership interest, the fact that we have been the largest Agenus stockholder since the date of our initial stock purchase, the level of intra-entity transactions between us and Agenus related to development expenses, as well as other qualitative factors. We have elected the fair value option to account for our long term investment in Agenus Inc. whereby the investment is marked to market through earnings in each reporting period. We believe the fair value option to be the most appropriate accounting method to account for securities in publicly held collaborators for which we have significant influence. For the three and nine months ended September 30, 2017, we recorded an unrealized gain of $10.2 million and $6.8 million, respectively, based on the change in fair value of our investment in Agenus common stock during these periods. For the three and nine months ended September 30, 2016, we recorded an unrealized gain of $24.3 million and $20.5 million, respectively, based on the change in fair value of our investment in Agenus common stock during these periods. The fair market value of our long term investment in Agenus was $78.3 million at September 30, 2017 and $32.0 million at December 31, 2016. For the three and six months ended June 30, 2017, Agenus Inc. reported total revenues of $4.2 million and $31.2 million, respectively, and a net loss of $31.7 million and $48.8 million, respectively, within its consolidated financial statements.

Research and development expenses for the three and nine months ended September 30, 2017 also included $29.7 million and $48.6 million, respectively, of additional development costs incurred pursuant to the Agenus agreement. Research and development expenses for the three and nine months ended September 30, 2016 also included $3.9 million and $12.0 million, respectively, of additional development costs incurred pursuant to the Agenus agreement. At September 30, 2017 and December 31, 2016, a total of $3.5 million and $11.4 million,

respectively, of such costs were included in accrued and other liabilities on the condensed consolidated balance sheet.

Hengrui

In September 2015, we entered into a License and Collaboration Agreement with Jiangsu Hengrui Medicine Co., Ltd. ("Hengrui"). Under the terms of this agreement, we received exclusive development and commercialization

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rights worldwide, with the exception of Mainland China, Hong Kong, Macau and Taiwan, to INCSHR1210, an investigational PD-1 monoclonal antibody, and certain back-up compounds. INCSHR1210 is currently in clinical development.

Under the terms of this agreement, we paid Hengrui an upfront payment of $25.0 million in 2015 which was recorded in research and development expense on the condensed consolidated statement of operations. Hengrui is also eligible to receive potential milestone payments of up to $770.0 million, consisting of $90.0 million for regulatory approval milestones, $530.0 million for commercial performance milestones, and $150.0 million for a clinical superiority milestone. Also, Hengrui may be eligible to receive tiered royalties in the high-single digits to mid-double digits based on net sales in our territories. Each company will be responsible for costs relating to the development and commercialization of the PD-1 monoclonal antibody in their respective territories. The agreement will continue on a country-by-country basis until we have no royalty payment obligations with respect to such country or, if earlier, the termination of the agreement in accordance with its terms. The agreement may be terminated in its entirety by us for convenience, and may also be terminated under certain other circumstances, including material breach.

Research and development expenses for the three and nine months ended September 30, 2017 included $0.4 million and $2.0 million, respectively, of development costs incurred pursuant to the Hengrui agreement. Research and development expenses for the three and nine months ended September 30, 2016 included $3.3 million and $5.5 million, respectively, of development costs incurred pursuant to the Hengrui agreement.

Merus

In December 2016, we entered into a Collaboration and License Agreement with Merus N.V. Under this agreement, which became effective in January 2017, the parties have agreed to collaborate with respect to the research, discovery and development of bispecific antibodies utilizing Merus' technology platform. The collaboration encompasses up to eleven independent programs, including two of Merus' current preclinical immuno-oncology discovery programs. We received exclusive development and commercialization rights outside of the United States to products and product candidates resulting from one of Merus' current preclinical discovery programs, referred to as "Program 1." We also received worldwide exclusive development and commercialization rights to products and product candidates resulting from the other current Merus preclinical discovery program that is subject to the collaboration and to up to nine additional programs. Merus retained exclusive development and commercialization rights in the United States to products and product candidates resulting from Program 1 and options, subject to certain conditions, to co-fund development of products resulting from two other programs in exchange for a share of profits in the United States. Should Program 1 fail to successfully complete IND-enabling toxicology studies, Merus would be granted an additional option to co-fund development of a program in exchange for a share of profits in the United States. All costs related to the collaboration are subject to joint research and development plans. Each party will share equally the costs of mutually agreed global development activities for Program 1, and fund itself any independent development activities in its territory. We will be responsible for all research, development and commercialization costs relating to all other programs, subject to Merus' election to co-fund development and co-detail described above. If Merus exercises its co-funding option for a program, Merus would be responsible for funding 35% of the associated future global development costs and, for certain of such programs, would be responsible for reimbursing us for certain development costs incurred prior to the option exercise.

In February 2017, we paid Merus an upfront non-refundable payment of $120.0 million, which is recorded in research and development expense on the condensed consolidated statement of operations. For each program as to which Merus does not have commercialization or co-development rights, Merus will be eligible to receive up to $100.0 million in future contingent development and regulatory milestones and up to $250.0 million in commercialization milestones as well as tiered royalties ranging from 6% to 10% of global net sales. For each program as to which Merus exercises its option to co-fund development, Merus will be eligible to receive a 50% share of profits (or sustain

50% of any losses) in the United States and be eligible to receive tiered royalties ranging from 6% to 10% of net sales of products outside of the United States. If Merus opts to cease co-funding a program as to which it exercised its co-development option, then Merus will no longer receive a share of profits in the United States but will be eligible to receive the same milestones from the co-funding termination date and the same tiered royalties described above with respect to non-co-developed programs and, depending on the stage at which Merus chose to cease co-funding development costs, additional royalties ranging up to

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4% of net sales in the United States. For Program 1, we and Merus will each be eligible to receive tiered royalties on net sales in the other party's territory at rates ranging from 6% to 10%.

The Merus agreement will continue on a program-by-program basis until we have no royalty payment obligations with respect to such program or, if earlier, the termination of the agreement or any program in accordance with the terms of the agreement. The agreement may be terminated in its entirety or on a program-by-program basis by us for convenience. The agreement may also be terminated by either party under certain other circumstances, including material breach, as set forth in the agreement. If the agreement is terminated with respect to one or more programs, all rights in the terminated programs revert to Merus, subject to payment to us of a reverse royalty of up to 4% on sales of future products, if Merus elects to pursue development and commercialization of products arising from the terminated programs.

In addition, in December 2016, we entered into a Share Subscription Agreement with Merus, pursuant to which we agreed to purchase 3.2 million common shares of Merus for an aggregate purchase price of $80.0 million in cash, or $25.00 per share.

We agreed to certain standstill provisions whereby we are obligated to refrain from taking certain actions with respect to Merus or Merus' common shares during a period ending on the earliest of (a) three years from the closing date of our share purchase, (b) the date Merus publicly announces any merger or similar business combination or another party announces an intention to acquire a substantial portion of Merus' securities, and (c) the termination of the Collaboration and License Agreement. The standstill provisions are subject to certain exceptions, including an exception that allows us to maintain our percentage ownership following equity financings by Merus. We also agreed, subject to limited exceptions, not to sell or otherwise transfer any of our Merus shares for a period, referred to as the Lock-Up Period, ending on the earlier of 18 months after the closing date of the sale of the Shares or the end of the standstill period. In addition, if the standstill period has not been terminated earlier upon the occurrence of certain events, for a period of three years after the Lock-Up Period, we will be restricted from selling or otherwise transferring more than one-third of our Merus shares during any 12-month period or 10% of our Merus shares during any three-month period, unless Merus consents otherwise. We have further agreed that during the standstill period, we will vote all of our Merus shares in accordance with the recommendation of a majority of Merus' supervisory board. However, we may vote our Merus shares at our own discretion for certain extraordinary matters, including a change in control of Merus. Merus has agreed to customary resale registration rights with respect to our Merus shares; however, any such resales will be subject to the Lock-Up Period and volume limitations on sale and transfer described above.

We completed the purchase of the shares on January 23, 2017 when the closing price on The NASDAQ Stock Market for Merus shares was $24.50 per share. The shares we acquired were not registered under the Securities Act of 1933 on the purchase date and are subject to certain security specific restrictions for a period of time, and accordingly, we estimated a discount for lack of marketability on the shares on the issuance date of $5.6 million, which resulted in a total fair value of the shares on the issuance date of $72.8 million. Of the total consideration paid of $80.0 million, $72.8 million was allocated to our stock purchase in Merus and was recorded as a long term investment on the condensed consolidated balance sheets and $7.2 million was allocated to research and development expense on the condensed consolidated statement of operations during the nine months ended September 30, 2017. The fair market value of our total long term investment in Merus was $63.6 million as of September 30, 2017.

We have concluded Merus is not a VIE because it has sufficient equity to finance its activities without additional subordinated financial support and its at-risk equity holders have the characteristics of a controlling financial interest. As of September 30, 2017, we owned approximately 17% of the outstanding shares of Merus common stock and conclude that we have the ability to exercise significant influence, but not control, over Merus based primarily on our ownership interest, the level of intra-entity transactions between us and Merus related to development expenses, as

well as other qualitative factors. We have elected the fair value option to account for our long term investment in Merus whereby the investment is marked to market through earnings in each reporting period. We believe the fair value option to be the most appropriate accounting method to account for securities in publicly held collaborators for which we have significant influence. For the three months ended September 30, 2017, we recorded an unrealized gain of $12.9 million and for the nine months ended September 30, 2017 we recorded an unrealized loss of $9.2 million, based on the change in fair value of Merus' common stock during these periods.

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Research and development expenses for the three and nine months ended September 30, 2017 included $1.7 million and $4.3 million, respectively, of additional development costs incurred pursuant to the Merus agreement. At September 30, 2017, a total of $1.8 million of such costs were included in accrued and other liabilities on the condensed consolidated balance sheet.

Calithera

In January 2017, we entered into a Collaboration and License Agreement with Calithera Biosciences, Inc. Under this agreement, we received an exclusive, worldwide license to develop and commercialize small molecule arginase inhibitors, including CB-1158, which is currently in phase I clinical trials, for hematology and oncology indications. We have agreed to co-fund 70% of the global development costs for the development of the licensed products for hematology and oncology indications. Calithera will have the right to conduct certain clinical development under the collaboration, including combination studies of a licensed product with a proprietary compound of Calithera. We will be entitled to 60% of the profits and losses from net sales of licensed product in the United States, and Calithera will have the right to co-detail licensed products in the United States, and we have agreed to pay Calithera tiered royalties ranging from the low to mid-double digits on net sales of licensed products outside the United States. Calithera may opt out of its co-funding obligation, in which case the U.S. profit sharing will no longer be in effect, and we have agreed to pay Calithera tiered royalties ranging from the low to mid-double digits on net sales of licensed products both in the United States and outside the United States, and additional royalties to reimburse Calithera for previously incurred development costs.

In January 2017, we paid Calithera an upfront license fee of $45.0 million and have agreed to pay potential development, regulatory and sales milestone payments of over $430.0 million if the profit share is in effect, or $750.0 million if the profit share terminates.

The Calithera agreement will continue on a product-by-product and country-by-country basis for so long as we are developing or commercializing products in the United States (if the parties are sharing profits in the United States) and until we have no further royalty payment obligations, unless earlier terminated according to the terms of the agreement. The agreement may be terminated in its entirety or on a product-by-product and/or a country-by-country basis by us for convenience. The agreement may also be terminated by us for Calithera's uncured material breach, by Calithera for our uncured material breach and by either party for bankruptcy or patent challenge. If the agreement is terminated early with respect to one or more products or countries, all rights in the terminated products and countries revert to Calithera.

In addition, in January 2017, we entered into a Stock Purchase Agreement with Calithera for the purchase of 1,720,430 common shares of Calithera for an aggregate purchase price of $8.0 million in cash, or $4.65 per share. We completed the purchase of the shares on January 30, 2017 when the closing price on The NASDAQ Stock Market was $6.75 per share. The shares we acquired were registered under the Securities Act of 1933 on the purchase date and there are no security specific restrictions for these shares, and therefore the value of the 1.7 million shares acquired by us was $11.6 million. We paid total consideration of $53.0 million to Calithera, composed of the $45.0 million upfront license fee and the $8.0 million stock purchase price. Of the $53.0 million, $11.6 million was allocated to our stock purchase in Calithera and was recorded within long term investments on the condensed consolidated balance sheets and $41.4 million was allocated to research and development expense on the condensed consolidated statement of operations during the nine months ended September 30, 2017. The fair market value of our long term investment in Calithera is $27.1 million as of September 30, 2017.

We have concluded Calithera is not a VIE because it has sufficient equity to finance its activities without additional subordinated financial support and its at-risk equity holders have the characteristics of a controlling financial interest. As of September 30, 2017, we owned approximately 5% of the outstanding shares of Calithera common

stock and there are several other stockholders who hold larger positions of Calithera. As we do not hold a significant position of the voting shares of Calithera and lack the qualitative characteristics associated with the ability to exercise significant influence, our ownership interest does not meet the criteria to be accounted for as an equity method investment. We intend to hold the investment in Calithera for the foreseeable future and therefore, we are accounting for our shares held in Calithera as an available-for-sale investment, whereby the investment is marked to market each period with unrealized gains and losses recorded in accumulated other comprehensive income (loss). Given our intent to hold the investment for the foreseeable future, we have classified the investment within long term investments on the accompanying balance sheet.

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For the three and nine months ended September 30, 2017, we recorded an unrealized gain of $1.5 million and $15.5 million, respectively, within other comprehensive income based on the change in fair value of Calithera's common stock during these periods.

In March 2017, Calithera earned a $12.0 million milestone payment from us for the achievement of pharmacokinetic and pharmacodynamics goals for CB-1158 which is recorded in research and development expense on our condensed consolidated statement of operations during the nine months ended September 30, 2017. Research and development expenses for the three and nine months ended September 30, 2017 also included $2.3 million and $5.9 million, respectively, of additional development costs incurred pursuant to the Calithera agreement. At September 30, 2017, a total of $2.0 million of such costs were included in accrued and other liabilities on the condensed consolidated balance sheet.

10. Stock compensation

We recorded $34.9 million and $99.3 million of stock compensation expense on our condensed consolidated statements of operations for the three and nine months ended September 30, 2017, respectively. We recorded $26.5 million and $68.6 million of stock compensation expense on our condensed consolidated statements of operations for the three and nine months ended September 30, 2016, respectively. Stock compensation expense included within our condensed consolidated statements of operations included research and development expense of $23.4 million, $67.8 million, $16.2 million and $42.8 million for the three and nine months ended September 30, 2017 and 2016, respectively. Stock compensation expense included within our condensed consolidated statements of operations also included selling, general and administrative expense of $11.5 million, $31.5 million, $10.3 million and $25.8 million for the three and nine months ended September 30, 2017 and 2016, respectively.

We utilized the Black-Scholes valuation model for estimating the fair value of the stock compensation granted, with the following weighted-average assumptions:

	Employee Stock Options				Employee Stock Purchase Plan			
	For the Three Months Ended September 30,		For the Nine Months Ended		For the Three Months Ended September 30,		For the Nine Months Ended	
	2017	2016	2017	2016	2017	2016	2017	2016
Average risk-free interest rates	1.81 %	1.05 %	1.79 %	1.31 %	1.47 %	0.77 %	1.37 %	0.77 %
Average expected life (in years)	4.99	4.96	5.24	4.99	0.50	0.50	0.50	0.50
Volatility	48 %	50 %	49 %	50 %	39 %	38 %	41 %	48 %
Weighted-average fair value (in dollars)	55.80	36.66	53.81	39.29	20.46	18.33	19.89	18.94

The risk-free interest rate is derived from the U.S. Federal Reserve rate in effect at the time of grant. The expected life calculation is based on the observed and expected time to the exercise of options by our employees based on historical exercise patterns for similar type options. Expected volatility is based on the historical volatility of our common stock over the period commensurate with the expected life of the options. A dividend yield of zero is assumed based on the fact that we have never paid cash dividends and have no present intention to pay cash dividends.

Option activity under the 2010 Stock Plan was as follows:

		Shares Subject to Outstanding Options	
	Shares Available for Grant	Shares	Weighted Average Exercise Price
Balance at December 31, 2016	6,327,138	11,504,572	$ 48.40
Options granted	(2,437,233)	2,437,233	$ 120.15
Options exercised	—	(2,546,517)	$ 30.68
Options cancelled	116,586	(116,586)	$ 96.30
Balance at September 30, 2017	4,006,491	11,278,702	$ 67.41

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In July 2016, we revised the terms of our annual stock option grants to provide that new option grants would generally have a 10-year term and vest over four years, with 25% vesting after one year and the remainder vesting in 36 equal monthly installments. Previously, our option grants generally had 7-year terms and vested over three years, with 33% vesting after one year and the remainder vesting in 24 equal monthly installments.

Restricted stock unit ("RSU") and performance share ("PSU") award activity under the 2010 Stock Plan was as follows:

	Shares Available for Grant	Shares Subject to Outstanding Awards Shares	Grant Date Value
Balance at December 31, 2016	1,146,152	1,246,570	$ 82.05
RSUs granted	(396,331)	396,331	$ 126.45
RSUs cancelled	41,376	(41,376)	$ 89.68
RSUs released	—	(382,133)	$ 127.72
PSUs released	—	(43,376)	$ 122.29
Balance at September 30, 2017	791,197	1,176,016	$ 100.86

In January 2014, we began granting RSUs and PSUs to our employees at the share price on the date of grant. Each RSU represents the right to acquire one share of our common stock. Each RSU granted prior to July 2016 was subject to cliff vesting after three years. In July 2016, we revised the terms of our RSU grants to provide that the awards will vest 25% annually over four years.

Also, in January 2014, Hervé Hoppenot, our President and Chief Executive Officer, was granted a one-time grant of 400,000 RSUs outside of our 2010 Stock Incentive Plan. Vesting of the RSUs will be subject to Mr. Hoppenot's continued employment on the applicable vesting dates, with one-sixth of the RSUs vesting at the end of each of the calendar years 2014 through 2019, subject to earlier acceleration of vesting upon the occurrence of certain events in accordance with the terms of his employment agreement. As of September 30, 2017, a cumulative total of 200,000 RSUs granted to Mr. Hoppenot had vested and were released, leaving 200,000 RSUs outstanding.

Based on our historical experience of employee turnover, we have assumed an annualized forfeiture rate of 5% for our options and RSUs. Under the true-up provisions of the stock compensation guidance, we will record additional expense if the actual forfeiture rate is lower than we estimated, and will record a recovery of prior expense if the actual forfeiture is higher than we estimated.

Total compensation cost of options granted but not yet vested, as of September 30, 2017, was $110.4 million, which is expected to be recognized over the weighted average period of approximately 1.6 years. Total compensation cost of RSUs granted but not yet vested, as of September 30, 2017, was $65.0 million, which is expected to be recognized over the weighted average period of approximately 1.6 years. There were no unvested PSUs as of September 30, 2017.

The following table summarizes our share activity:

	Shares Issued and Outstanding

Balance at December 31, 2016	188,848,752
Exercise of stock options and issuance under ESPP	2,643,324
Settlement of employee restricted stock units and performance shares	285,958
Conversion of convertible senior notes	14,296,332
Public issuance of common stock	4,945,000
Balance at September 30, 2017	211,019,366

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11. Common stock offering

On September 7, 2017, we completed a public offering of 4,945,000 shares of our authorized but unissued common stock pursuant to an effective shelf registration statement. The underwriter had an option for a period of 30 days to purchase a maximum of 741,750 additional shares of our common stock, which expired unexercised. We sold the shares of common stock to the underwriter at a price of $131.46 per share, resulting in net proceeds, after deducting expenses related to the offering, of approximately $649.4 million.

12. Debt

The components of the convertible notes are as follows (in thousands):

Debt	Interest Rates September 30, 2017		Maturities	Carrying Amount, September 30, 2017	Carrying Amount, December 31, 2016
0.375% Convertible Senior Notes due 2018	0.375	%	2018	$ 7,303	$ 340,916
1.25% Convertible Senior Notes due 2020	1.25	%	2020	16,408	310,565
				23,711	651,481
Less current portion				—	—
				$ 23,711	$ 651,481

The carrying amount and fair value of our convertible notes are as follows (in thousands):

	September 30, 2017		December 31, 2016	
	Carrying Amount	Fair Value	Carrying Amount	Fair Value
0.375% Convertible Senior Notes due 2018	$ 7,303	$ 17,467	$ 340,916	$ 749,988
1.25% Convertible Senior Notes due 2020	16,408	43,534	310,565	761,300
	$ 23,711	$ 61,001	$ 651,481	$ 1,511,288

The fair values of the 0.375% Convertible Senior Notes due 2018 (the “2018 Notes”) and the 1.25% Convertible Senior Notes due 2020 (the “2020 Notes”) are based on data from readily available pricing sources which utilize market observable inputs and other characteristics for similar types of instruments, and, therefore, these convertible senior notes are classified within Level 2 in the fair value hierarchy.

Prior to May 14, 2014, the 2018 and 2020 Notes were not convertible except in connection with a make whole fundamental change, as defined in the respective indentures. Beginning on, and including, May 15, 2014, the 2018 and 2020 Notes are convertible prior to the close of business on the business day immediately preceding May 15, 2018, in the case of the 2018 Notes, and May 15, 2020, in the case of the 2020 Notes, only under the following circumstances: (1) during any calendar quarter commencing after the calendar quarter ending on March 31, 2014 (and only during such calendar quarter), if the last reported sale price of our common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price for the 2018 Notes or 2020 Notes,

as applicable, on each applicable trading day; (2) during the five business day period after any five consecutive trading day period (the "measurement period") in which the trading price per $1,000 principal amount of 2018 Notes or 2020 Notes, as applicable, for each trading day of the measurement period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate for the 2018 Notes or 2020 Notes, as applicable, on each such trading day; or (3) upon the occurrence of specified corporate events. On or after May 15, 2018, in the case of the 2018 Notes, and May 15, 2020, in the case of the 2020 Notes, until the close of business on the second scheduled trading day immediately preceding the relevant maturity date, the Notes are convertible at any time, regardless of the foregoing circumstances. Upon conversion we will pay or deliver, as the case may be, cash, shares of common stock or a combination of cash and shares of common stock, at our election.

On October 1, 2017, the 2018 Notes and 2020 Notes became convertible through at least December 31, 2017, based on meeting the conversion criteria related to the sale price of our common stock during the calendar quarter ended

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September 30, 2017 as described in (1) above. Management's intent is to settle any conversions of 2018 Notes or 2020 Notes during this period in shares of our common stock and, therefore, the 2018 Notes and 2020 Notes are reflected in long term liabilities on the condensed consolidated balance sheet at September 30, 2017.

During the nine months ended September 30, 2017, we entered into separately negotiated agreements with certain holders of the 2018 Notes pursuant to which such holders agreed to exchange a total of $367.2 million in aggregate principal amount of the 2018 Notes for the shares of our common stock into which the 2018 Notes were originally convertible, aggregating 7.1 million shares, an additional 0.1 million of premium shares (equivalent to $12.6 million in value) and $2.0 million in cash. Similarly we entered into separately negotiated agreements with certain holders of the 2020 Notes pursuant to which such holders agreed to exchange a total of $355.6 million in aggregate principal amount of the 2020 Notes for the shares of our common stock into which the 2020 Notes were originally convertible, aggregating 6.9 million shares, an additional 0.2 million of premium shares (equivalent to $26.8 million in value) and $7.0 million in cash. Included in the agreements were those with entities affiliated with Julian C. Baker, one of our directors, which agreed to exchange $259.0 million in aggregate principal amount of the 2018 Notes and $274.5 million in aggregate principal amount of the 2020 Notes for an aggregate of 10.6 million shares.

Pursuant to the guidance within the ASC 470-20-40-20, we measured the difference between the fair value and carrying value of the liability portion of the Notes which resulted in recording expense related to senior note conversions of $1.4 million related to the 2018 Notes and $5.1 million related to the 2020 Notes. The estimated fair value of the debt component was determined using a valuation model which is subject to judgement. Assumptions used within the valuation model include an estimated credit rating and an estimated market-based cost of debt. These assumptions were used to perform a discounted cash flow analysis on the future interest and principal payments to determine the estimated fair value of the debt at inducement.

In addition, the fair value of the premium shares issued pursuant to these agreements as well as the cash paid in connection with the agreements totaled $48.4 million and is also included within expense related to senior note conversions on the condensed consolidated statement of operations during the nine months ended September 30, 2017.

13. Defined benefit pension obligation

In connection with the Acquisition, we assumed a defined benefit pension plan for the former ARIAD employees. In addition, we established another defined benefit pension plan for other Incyte employees in Europe. The pension plans provide benefits to employees upon retirement, death or disability.

The net periodic benefit cost was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Service cost	$ 760	$ 365	$ 2,056	$ 503
Interest cost	57	29	155	39
Expected return on plan assets	(43)	(23)	(116)	(31)
Amortization of prior service cost	12	—	37	—
Amortization of actuarial losses	34	—	102	—
Net periodic benefit cost	$ 820	$ 371	$ 2,234	$ 511

We expect to contribute a total of $2.1 million to the plans in 2017 inclusive of the amounts contributed to the plan during the current period. As of September 30, 2017 and December 31, 2016, $7.3 million and $7.1 million,

respectively, of accrued pension obligation is recorded in other long term liabilities on the condensed consolidated balance sheets.

14. Income taxes

For the three and nine months ended September 30, 2017, we recorded income tax expense of approximately $7.3

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million and an income tax benefit of $0.5 million, respectively, compared to income tax expense of approximately $1.4 million and $2.6 million for the three and nine months ended September 30, 2016. The change in tax expense or benefit for the three and nine months ended September 30, 2017 and 2016 was primarily driven by the difference in projected annual operating income or loss compared to our actual results as well as the recognition of certain discrete items in the current period. As a result, our year-to-date recorded effective tax rate may differ significantly from our full year effective tax rate.

As of September 30, 2017, a full valuation allowance continues to be recorded against our U.S. and Swiss net deferred tax assets. This position is based on an analysis of positive and negative evidence, including analyzing three-year cumulative pre-tax income or loss, projections of future taxable income as well as other quantitative and qualitative information.

Our liability for unrecognized tax benefits (including penalties and interest) increased by approximately $3.6 million during the nine months ended September 30, 2017, of which only $0.6 million was recorded as an increase to noncurrent other liabilities on the condensed consolidated balance sheet. The increase is primarily driven by unrecognized tax benefits related to current year operations.

In October 2017, we secured an incentive tax holiday in Switzerland that exempts us from certain Swiss income taxes for a period of 10 years.

15. Net income (loss) per share

Net income (loss) per share was calculated as follows for the periods indicated:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands, except per share data)	2017	2016	2017	2016
Basic Net Income (Loss) Per Share				
Basic net income (loss)	$ 36,054	$ 36,877	$ (163,513)	$ 95,349
Weighted average common shares outstanding	206,796	188,029	202,399	187,632
Basic net income (loss) per share	$ 0.17	$ 0.20	$ (0.81)	$ 0.51
Diluted Net Income (Loss) Per Share				
Diluted net income (loss)	$ 36,054	$ 36,877	$ (163,513)	$ 95,349
Weighted average common shares outstanding	206,796	188,029	202,399	187,632
Dilutive stock options and RSUs	5,814	6,236	—	6,122
Weighted average shares used to compute diluted net income (loss) per share	212,610	194,265	202,399	193,754
Diluted net income (loss) per share	$ 0.17	$ 0.19	$ (0.81)	$ 0.49

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The following potential common shares were excluded from the calculations as their effect would be anti-dilutive:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Outstanding stock options and awards	2,399,468	3,119,097	12,654,718	2,947,152
Common shares issuable upon conversion of the 2018 Notes	149,527	7,245,206	149,527	7,245,206
Common shares issuable upon conversion of the 2020 Notes	368,939	7,241,284	368,939	7,241,284
Total potential common shares excluded from diluted net loss per share computation	2,917,934	17,605,587	13,173,184	17,433,642

16. Contingencies

In February 2016, we received a Paragraph IV certification notice (the “Notice Letter”) regarding an Abbreviated New Drug Application submitted to the U.S. Food and Drug Administration requesting approval to market a generic version of Jakafi (ruxolitinib). The Notice Letter purports to challenge patents covering ruxolitinib phosphate and its use that expire in 2028. The Notice Letter does not challenge the ruxolitinib composition of matter patent, which expires on December 24, 2027. We do not believe there is any kind of loss that is probable or estimable related to this matter at this time.

17. Subsequent Events

MacroGenics

In October 2017, we entered into a Global Collaboration and License Agreement (the “Agreement”) with MacroGenics, Inc. (“MacroGenics”). Under the terms of the Agreement, we received exclusive development and commercialization rights worldwide to MGA012, an investigational monoclonal antibody that inhibits programmed cell death protein 1 (PD 1). MGA012 is currently in clinical development by MacroGenics. We have agreed to pay MacroGenics an upfront payment of $150.0 million. MacroGenics will be eligible to receive up to $420.0 million in future contingent development and regulatory milestones and up to $330.0 million in commercialization milestones as well as tiered royalties ranging from 15% to 24% of global net sales. The effectiveness of the Agreement is conditioned on the early termination or expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976; provided, that certain provisions, including those relating to indemnification and termination for material breach, became effective upon execution of the Agreement.

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

The following discussion of our financial condition and results of operations as of and for the three and nine months ended September 30, 2017 should be read in conjunction with the unaudited condensed consolidated financial statements and notes to those statements included elsewhere in this Quarterly Report on Form 10-Q and our audited consolidated financial statements as of and for the year ended December 31, 2016 included in our Annual Report on Form 10-K for the year ended December 31, 2016 previously filed with the SEC.

This report contains forward-looking statements that involve risks and uncertainties. These statements relate to future periods, future events or our future operating or financial plans or performance. Often, these statements include the words "believe," "expect," "target," "anticipate," "intend," "plan," "seek," "estimate," "potential," or words of similar meaning or conditional verbs such as "will," "would," "should," "could," "might," or "may," or the negative of these terms, and other similar expressions. These forward-looking statements include statements as to:

- the discovery, development, formulation, manufacturing and commercialization of our compounds, our drug candidates and JAKAFI®/JAKAVI® (ruxolitinib) and ICLUSIG® (ponatinib);

- the expected benefits from our acquisition of ARIAD Pharmaceuticals (Luxembourg) S.à.r.l. and our plans to further develop our European operations;

- conducting clinical trials internally, with collaborators, or with clinical research organizations;
- our collaboration and strategic relationship strategy; anticipated benefits and disadvantages of entering into collaboration agreements;
- our licensing, investment and commercialization strategies, including our plans to commercialize JAKAFI and ICLUSIG;
- the regulatory approval process, including obtaining U.S. Food and Drug Administration and other international health authorities approval for our products in the United States and abroad;
- the safety, effectiveness and potential benefits and indications of our drug candidates and other compounds under development;
- the timing and size of our clinical trials; the compounds expected to enter clinical trials; timing of clinical trial results;
- our ability to manage expansion of our drug discovery and development operations;
- future required expertise relating to clinical trials, manufacturing, sales and marketing;
- obtaining and terminating licenses to products, drug candidates or technology, or other intellectual property rights;
- the receipt from or payments pursuant to collaboration or license agreements resulting from milestones or royalties;
- plans to develop and commercialize products on our own;
- plans to use third party manufacturers;
- expected expenses and expenditure levels; expected uses of cash; expected revenues and sources of revenues, including milestone payments; expectations with respect to inventory;

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- expectations with respect to reimbursement for our products;

- the expected impact of recent accounting pronouncements;

- expected losses; fluctuation of losses; currency translation impact associated with collaboration royalties;
- our profitability; the adequacy of our capital resources to continue operations;
- the need to raise additional capital;
- the costs associated with resolving matters in litigation;
- our expectations regarding competition;
- our investments, including anticipated expenditures, losses and expenses;
- our patent prosecution and maintenance efforts; and
- our indebtedness, and debt service obligations.

These forward looking statements reflect our current views with respect to future events, are based on assumptions and are subject to risks and uncertainties. These risks and uncertainties could cause actual results to differ materially from those projected and include, but are not limited to:

- our ability to successfully commercialize JAKAFI and ICLUSIG;
- our ability to maintain at anticipated levels reimbursement for our products from government health administration authorities, private health insurers and other organizations;

- our ability to establish and maintain effective sales, marketing and distribution capabilities;

- the risk of reliance on other parties to manufacture our products, which could result in a short supply of our products, increased costs, and withdrawal of regulatory approval;

- our ability to maintain regulatory approvals to market our products;

- our ability to achieve a significant market share in order to achieve or maintain profitability;

- the risk of civil or criminal penalties if we market our products in a manner that violates health care fraud and abuse and other applicable laws, rules and regulations;

- our ability to discover, develop, formulate, manufacture and commercialize our drug candidates;
- the risk of unanticipated delays in, or discontinuations of, research and development efforts;
- the risk that previous preclinical testing or clinical trial results are not necessarily indicative of future clinical trial results;
- risks relating to the conduct of our clinical trials;
- changing regulatory requirements;
- the risk of adverse safety findings;

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- the risk that results of our clinical trials do not support submission of a marketing approval application for our drug candidates;
- the risk of significant delays or costs in obtaining regulatory approvals;
- risks relating to our reliance on third party manufacturers, collaborators, and clinical research organizations;
- risks relating to the development of new products and their use by us and our current and potential collaborators;
- risks relating to our inability to control the development of out licensed compounds or drug candidates;
- risks relating to our collaborators' ability to develop and commercialize drug candidates;
- costs associated with prosecuting, maintaining, defending and enforcing patent claims and other intellectual property rights;
- our ability to maintain or obtain adequate product liability and other insurance coverage;
- the risk that our drug candidates may not obtain or maintain regulatory approval;
- the impact of technological advances and competition, including potential generic competition;
- our ability to compete against third parties with greater resources than ours;
- risks relating to changes in pricing and reimbursement in the markets in which we may compete;
- competition to develop and commercialize similar drug products;
- our ability to obtain and maintain patent protection and freedom to operate for our discoveries and to continue to be effective in expanding our patent coverage;
- the impact of changing laws on our patent portfolio;
- developments in and expenses relating to litigation;
- the satisfaction of conditions to closing for land purchase agreements;
- our ability to in license drug candidates or other technology;
- our ability to integrate successfully acquired businesses, development programs or technology;
- our substantial leverage;
- our ability to obtain additional capital when needed;
- fluctuations in net cash provided and used by operating, financing and investing activities;
- our ability to analyze the effects of new accounting pronouncements and apply new accounting rules;
- our history of operating losses; and

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· the risks set forth under "Risk Factors."

Given these risks and uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by federal securities laws, we undertake no obligation to update any forward-looking statements for any reason, even if new information becomes available or other events occur in the future.

In this report all references to "Incyte," "we," "us," "our" or the "Company" mean Incyte Corporation and our subsidiaries, except where it is made clear that the term means only the parent company.

Incyte and JAKAFI are our registered trademarks. We also refer to trademarks of other corporations and organizations in this Quarterly Report on Form 10-Q.

Overview

Incyte is a biopharmaceutical company focused on the discovery, development and commercialization of proprietary therapeutics. Our global headquarters is located in Wilmington, Delaware. We conduct our European clinical development operations from our offices in Geneva, Switzerland, and Lausanne, Switzerland, and have recently opened our Japanese office in Tokyo.

Marketed Indications - JAKAFI (ruxolitinib)

JAKAFI (ruxolitinib) is our first product to be approved for sale in the United States. It was approved by the U.S. Food and Drug Administration (FDA) in November 2011 for the treatment of patients with intermediate or high risk myelofibrosis and in December 2014 for the treatment of patients with polycythemia vera who have had an inadequate response to or are intolerant of hydroxyurea. Myelofibrosis and polycythemia vera are both rare blood cancers. Under our collaboration agreement with Novartis International Pharmaceutical Ltd., Novartis received exclusive development and commercialization rights to ruxolitinib outside of the United States for all hematologic and oncologic indications and sells ruxolitinib outside of the United States under the name JAKAVI.

In 2003, we initiated a research and development program to explore the inhibition of enzymes called janus associated kinases (JAK). The JAK family is composed of four tyrosine kinases—JAK1, JAK2, JAK3 and Tyk2—that are involved in the signaling of a number of cytokines and growth factors. JAKs are central to a number of biologic processes, including the formation and development of blood cells and the regulation of immune functions. Dysregulation of the JAK STAT signaling pathway has been associated with a number of diseases, including myeloproliferative neoplasms, other hematological malignancies, rheumatoid arthritis and other chronic inflammatory diseases. Myeloproliferative neoplasms are a closely related group of blood diseases in which blood cells, specifically platelets, white blood cells, and red blood cells, grow or act abnormally. These diseases include myelofibrosis (MF), polycythemia vera (PV) and essential thrombocythemia (ET).

We have discovered multiple potent, selective and orally bioavailable JAK inhibitors that are selective for JAK1 or JAK1 and JAK2. JAKAFI is the most advanced compound in our JAK program. It is an oral JAK1 and JAK2 inhibitor.

JAKAFI is marketed in the United States through our own specialty sales force and commercial team. JAKAFI was the first FDA approved JAK inhibitor for any indication and was the first and remains the only product approved by the FDA for use in MF and PV. The FDA has granted JAKAFI orphan drug status for MF, PV, ET, acute lymphoblastic leukemia (ALL) and graft-versus-host-disease (GVHD).

To help ensure that all eligible MF and PV patients have access to JAKAFI, we have established a patient assistance program called IncyteCARES (CARES stands for Connecting to Access, Reimbursement, Education and Support).

IncyteCARES helps ensure that any patient with intermediate or high risk MF or uncontrolled PV who meets certain eligibility criteria and is prescribed JAKAFI has access to the product regardless of ability to pay and has access to ongoing support and educational resources during treatment. In addition, IncyteCARES works closely with payers to help facilitate insurance coverage of JAKAFI.

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JAKAFI is distributed primarily through a network of specialty pharmacy providers and wholesalers that allow for efficient delivery of the medication by mail directly to patients or direct delivery to the patient's pharmacy. Our distribution process uses a model that is well established and familiar to physicians who practice within the oncology field.

To further support appropriate use and future development of JAKAFI, our U.S. Medical Affairs department is responsible for providing appropriate scientific and medical education and information to physicians, preparing scientific presentations and publications, and overseeing the process for supporting investigator sponsored trials.

Myelofibrosis. Myelofibrosis is a rare, life threatening condition. MF, considered the most serious of the myeloproliferative neoplasms, can occur either as primary MF, or as secondary MF that develops in some patients who previously had polycythemia vera or essential thrombocythemia. We estimate there are between 16,000 and 18,500 patients with MF in the United States. Based on the modern prognostic scoring systems referred to as International Prognostic Scoring System and Dynamic International Prognostic Scoring System, we believe intermediate and high risk patients represent 80% to 90% of all patients with MF in the United States and encompass patients over the age of 65, or patients who have or have ever had any of the following: anemia, constitutional symptoms, elevated white blood cell or blast counts, or platelet counts less than 100,000 per microliter of blood.

Most MF patients have enlarged spleens and many suffer from debilitating symptoms, including abdominal discomfort, pruritus (itching), night sweats and cachexia (involuntary weight loss). There were no FDA approved therapies for MF until the approval of JAKAFI.

The FDA approval was based on results from two randomized Phase III trials (COMFORT I and COMFORT II), which demonstrated that patients treated with JAKAFI experienced significant reductions in splenomegaly (enlarged spleen). COMFORT I also demonstrated improvements in symptoms. The most common hematologic adverse reactions in both trials were thrombocytopenia and anemia. These events rarely led to discontinuation of JAKAFI treatment. The most common non hematologic adverse reactions were bruising, dizziness and headache.

In August 2014, the FDA approved supplemental labeling for JAKAFI to include Kaplan Meier overall survival curves as well as additional safety and dosing information. The overall survival information is based on three year data from COMFORT I and II, and shows that at three years the probability of survival for patients treated with JAKAFI in COMFORT I was 70% and for those patients originally randomized to placebo it was 61%. In COMFORT II, at three years the probability of survival for patients treated with JAKAFI was 79% and for patients originally randomized to best available therapy it was 59%. In December 2016, we announced an exploratory pooled analysis of data from the five-year follow-up of the COMFORT-I and COMFORT-II trials of patients treated with JAKAFI, which further supported previously published overall survival findings.

In October 2017, the FDA approved updated labeling for JAKAFI to include the addition of new patient-reported outcome (PRO) data from the COMFORT-I study, as well as updating the warning related to progressive multifocal leukoencephalopathy. An exploratory analysis of PRO data of patients with myelofibrosis receiving JAKAFI showed improvement in fatigue-related symptoms at Week 24. Fatigue response (defined as a reduction of 4.5 points or more from baseline in the PROMIS® Fatigue total score) was reported in 35% of patients treated with JAKAFI versus 14% of the patients treated with placebo.

In September 2016, we announced that JAKAFI had been included as a recommended treatment in the latest National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology for myelofibrosis, underscoring the important and long-term clinical benefits seen in patients treated with JAKAFI.

Polycythemia Vera. PV is a myeloproliferative neoplasm typically characterized by elevated hematocrit, the volume percentage of red blood cells in whole blood, which can lead to a thickening of the blood and an increased risk of blood clots, as well as an elevated white blood cell and platelet count. When phlebotomy can no longer control PV, chemotherapy such as hydroxyurea, or interferon, is utilized. Approximately 25,000 patients with PV in the United States are considered uncontrolled because they have an inadequate response to or are intolerant of hydroxyurea, the most commonly used chemotherapeutic agent for the treatment of PV.

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In December 2014, the FDA approved JAKAFI for the treatment of patients with PV who have had an inadequate response to or are intolerant of hydroxyurea. The approval of JAKAFI for PV was based on data from the pivotal Phase III RESPONSE trial. In this trial, patients treated with JAKAFI demonstrated superior hematocrit control and reductions in spleen volume compared to best available therapy. In addition, a greater proportion of patients treated with JAKAFI achieved complete hematologic remission—which was defined as achieving hematocrit control, and lowering platelet and white blood cell counts. In the RESPONSE trial, the most common hematologic adverse reactions (incidence > 20%) were thrombocytopenia and anemia. The most common non hematologic adverse events (incidence >10%) were headache, abdominal pain, diarrhea, dizziness, fatigue, pruritus, dyspnea and muscle spasms.

In March 2016, the FDA approved supplemental labeling for JAKAFI to include additional safety data as well as efficacy analyses from the RESPONSE trial to assess the durability of response in JAKAFI treated patients after 80 weeks. At this time, 83% patients were still on treatment, and 76% of the responders at 32 weeks maintained their response through 80 weeks.

In June 2016, we announced data from the Phase 3 RESPONSE-2 study of JAKAFI in patients with inadequately controlled PV that was resistant to or intolerant of hydroxyurea who did not have an enlarged spleen. These data showed that JAKAFI was superior to best available therapy in maintaining hematocrit control (62.2% vs. 18.7%, respectively; P<0.0001) without the need for phlebotomy.

In August 2017, we announced that JAKAFI had been included as a recommended treatment in the latest NCCN Guidelines for patients with polycythemia vera who have had an inadequate response to first-line therapies, such as hydroxyurea.

We have retained all development and commercialization rights to JAKAFI in the United States and are eligible to receive development and commercial milestones as well as royalties from product sales outside the United States. We hold patents that cover the composition of matter and use of ruxolitinib which patents, including applicable extensions, expire in late 2027.

Marketed Indications - ICLUSIG (ponatinib)

In June 2016, we acquired the European operations of ARIAD Pharmaceuticals, Inc (ARIAD) and obtained an exclusive license to develop and commercialize ICLUSIG (ponatinib) in Europe and other select countries. ICLUSIG is a kinase inhibitor. The primary target for ICLUSIG is BCR-ABL, an abnormal tyrosine kinase that is expressed in chronic myeloid leukemia (CML) and Philadelphia-chromosome positive acute lymphoblastic leukemia (Ph+ ALL).

In the European Union, ICLUSIG is approved for the treatment of adult patients with chronic phase, accelerated phase or blast phase chronic myeloid leukemia (CML) who are resistant to dasatinib or nilotinib; who are intolerant to dasatinib or nilotinib and for whom subsequent treatment with imatinib is not clinically appropriate; or who have the T315I mutation, or the treatment of adult patients with Philadelphia-chromosome positive acute lymphoblastic leukemia (Ph+ ALL) who are resistant to dasatinib; who are intolerant to dasatinib and for whom subsequent treatment with imatinib is not clinically appropriate; or who have the T315I mutation.

Clinical Programs in Oncology

We believe that the future of cancer treatment lies in the use of immune therapies, which seek to recruit the patient’s own immune system to tackle cancer, and targeted therapies, which aim to block, directly or indirectly, the effects of cancer-causing mutations. Our most advanced programs are detailed below.

We also have a number of other early programs at various stages of preclinical and clinical testing. We intend to describe these programs once we have obtained clinical proof of concept and established that a compound within a specific program warrants further development.

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Targeted Therapies

Building upon positive, independently published third-party data of ruxolitinib in GVHD, we have initiated the REACH clinical program to evaluate ruxolitinib in patients with steroid-refractory GVHD. REACH1, a pivotal Phase II trial in steroid-refractory acute GVHD was initiated in December 2016. REACH2, the Novartis-sponsored Phase III trial in steroid-refractory acute GVHD, and REACH3, the Phase III trial in steroid-refractory chronic GVHD that is co-sponsored by Incyte and Novartis, are both now underway. In June 2016, we announced that the FDA granted Breakthrough Therapy Designation for ruxolitinib in patients with acute GVHD. In April 2016, we announced an agreement with Eli Lilly and Company enabling us to develop and commercialize ruxolitinib in the United States for the treatment of GVHD. We also announced an agreement with Novartis granting Novartis exclusive research, development and commercialization rights for ruxolitinib in GVHD outside the United States.

A proof-of-concept trial of itacitinib, a selective JAK1 inhibitor, is ongoing for the treatment of patients with acute GVHD. Based on preliminary data from this trial, a pivotal program investigating itacitinib for the treatment of patients with treatment-naïve acute GVHD was initiated in July 2017. The FDA has granted itacitinib orphan drug status for GVHD.

GVHD is a condition that can occur after an allogeneic transplant (the transfer of genetically dissimilar stem cells or tissue). In GVHD, the donated bone marrow or peripheral blood stem cells view the recipient's body as foreign and attack the body. We estimate that the long-term survival in patients with corticosteroid-refractory GVHD is approximately 5% to 30% and that the diagnosed incidence of acute and chronic GVHD is approximately 17,000 per year across the United States and Europe.

Following positive proof-of-concept data, we have opened a pivotal program investigating ruxolitinib for the treatment of patients with essential thrombocythemia. ET is a Philadelphia chromosome negative myeloproliferative neoplasm, characterized by the overproduction of platelets in the bone marrow. The pivotal RESET-272 trial will enroll ET patients that are refractory to or intolerant of hydroxyurea, the current standard of care for first-line treatment of these patients.

We have a portfolio of wholly-owned selective JAK1 inhibitors, including itacitinib and INCB52793. The clinical program to evaluate itacitinib in solid tumors includes a clinical trial in combination with AstraZeneca/MedImmune's EGFR inhibitor osimertinib. INCB52793 is in a Phase I/II trial in patients with advanced malignancies.

The PI3K-delta pathway mediates oncogenic signaling in B cell malignancies. INCB50465 is a PI3K-delta inhibitor that has demonstrated potency and selectivity in preclinical studies and has potential therapeutic utility in the treatment of patients with lymphoma. We have initiated the CITADEL clinical program to evaluate INCB50465 in non-Hodgkin lymphomas, including patients with diffuse large b-cell lymphoma (DLBCL), follicular lymphoma, marginal zone lymphoma and mantle cell lymphoma.

INCB54828 is an inhibitor of the FGFR isoforms 1, 2 and 3 that has demonstrated potency and selectivity in preclinical studies. The FGFR family of receptor tyrosine kinases can act as oncogenic drivers in a number of liquid and solid tumor types. We initiated the FIGHT clinical program to evaluate INCB54828 across a spectrum of cancers that are driven by FGF/FGFR mutations. The program now has three Phase II trials enrolling – FIGHT-201 in patients with bladder cancer, FIGHT-202 in patients with cholangiocarcinoma, and FIGHT-203 in patients with 8p11 myeloproliferative syndrome (8p11 MPN).

BRDs are a family of proteins which play important roles in mediating gene transcription, most notably by facilitating the expression of oncogenes such as MYC, one of the most frequently dysregulated oncogenes in all human cancer. We have two BRD inhibitors, INCB54329 and INCB57643, in open-label dose-escalation trials in patients with

advanced malignancies. The evaluation of these two compounds has enabled an assessment of relative pharmacodynamics and, based on these emerging data, we have now decided to focus our development activities on INCB57643.

INCB53914 is a pan-PIM kinase inhibitor that has demonstrated potency and selectivity in preclinical studies. PIM kinases integrate signals from multiple pathways important for the survival and proliferation of malignant cells. Over

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expression of PIM kinases has been reported in human hematological cancers with each isoform showing a distinct expression pattern among the various malignancy subtypes. A clinical trial of INCB53914 in advanced malignancies is underway.

INCB59872 is an LSD1 inhibitor. LSD1 is a key enzyme that is involved in epigenetic regulation of gene transcription. Dysregulated LSD1 activity can perturb normal gene expression, leading to cellular transformation. In particular, the function of LSD1 has been reported to maintain stem cell-like gene expression patterns in various cancers, including acute myeloid leukemia and small cell lung cancer. A proof-of-concept clinical trial of INCB59872 is underway.

INCB62079 is a selective, irreversible inhibitor of FGFR4 that has exhibited 250 times greater selectivity for FGFR4 than other FGFR isoforms in preclinical studies. Preclinical data has also demonstrated the compound's selective activity against cancer cell lines with FGF19-FGFR4 pathway activation, and dose-dependent activity in murine models of FGF19-driven hepatocellular carcinoma. A Phase I/II dose escalation trial in patients with advanced hepatocellular carcinoma and other malignancies is now underway.

	Indication	Status Update
Ruxolitinib (JAK1/JAK2)	Steroid-refractory acute GVHD	Pivotal Phase II (REACH1); Phase III (REACH2)
Ruxolitinib (JAK1/JAK2)	Steroid-refractory chronic GVHD	Phase III (REACH3)
Ruxolitinib (JAK1/JAK2)	Essential thrombocythemia	Pivotal Phase II (RESET-272) open for enrollment
Itacitinib (JAK1)	Treatment-naïve acute GVHD	Phase III (GRAVITAS-301)
Itacitinib (JAK1)	Non-small cell lung cancer	Phase I/II in combination with osimertinib (EGFR)
INCB52793 (JAK1)	Advanced malignancies	Phase I/II dose-escalation
INCB50465 (PI3K)	Diffuse large b-cell lymphoma, follicular lymphoma, marginal zone lymphoma, mantle cell lymphoma	Phase II (CITADEL-202 initiated; CITADEL-203, CITADEL-204, CITADEL-205 all open for enrollment)
INCB54828 (FGFR1/2/3)	Bladder cancer, cholangiocarcinoma, 8p11 MPNs	Phase II (FIGHT-201, FIGHT-202, FIGHT-203)
INCB57643 (BRD)	Advanced malignancies	Phase I/II dose-escalation
INCB53914 (PIM)	Advanced malignancies	Phase I/II dose-escalation
INCB59872 (LSD1)	Acute myeloid leukemia, small cell lung cancer	Phase I/II dose-escalation
INCB62079 (FGFR4)	Hepatocellular carcinoma	Phase I/II dose-escalation

Immune Therapies

The enzyme indoleamine 2, 3 dioxygenase 1 (IDO1) is a key regulator of the mechanisms that are responsible for allowing tumors to escape from a patient's immune surveillance. IDO1 expression by tumor cells, or by antigen

presenting cells such as macrophages and dendritic cells in tumors, creates an environment in which tumor specific cytotoxic T lymphocytes are rendered functionally inactive or are no longer able to attack a patient's cancer cells. By inhibiting IDO1, it is proposed that this "brake" on the anti tumor immune response is removed, allowing anti tumor specific cytotoxic T cells, generated in a patient spontaneously in response to the tumor, or through a therapy designed to stimulate the immune response, to have greater anti tumor efficacy.

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Epacadostat is a novel, potent and selective inhibitor of the enzyme IDO1, and the ECHO clinical development program will investigate the development of epacadostat in combination with other therapeutic agents, including checkpoint inhibitors, vaccines, epigenetic therapies, and chemotherapies. During 2014, we signed clinical trial collaboration agreements with Merck, Bristol-Myers Squibb, AstraZeneca/MedImmune and Roche/Genentech to evaluate epacadostat with their respective anti-PD-1 and anti-PD-L1 agents, pembrolizumab, nivolumab, durvalumab and atezolizumab, respectively, in Phase I/II trials. We have global development and commercialization rights to epacadostat for all indications.

In October 2015, we and Merck announced an expansion of the companies' ongoing clinical trial collaboration to include ECHO-301, a Phase III study evaluating the combination of epacadostat with pembrolizumab as a first-line treatment for patients with advanced or metastatic melanoma. In July 2017, the FDA granted Fast Track designation to the ECHO-301 trial to demonstrate a statistically robust and clinically meaningful improvement in progression free survival and/or overall survival compared to patients treated with pembrolizumab alone.

In March 2017, we and Merck announced details of the companies' planned expansion of the ongoing clinical trial collaboration to include four additional tumor types, evaluating epacadostat plus pembrolizumab in patients with non-small cell lung (NSCLC), renal, bladder, and head & neck cancers. Initial regulatory feedback on the designs of these Phase III trials in additional tumor types has been received, and these trials are expected to be initiated in 2017. In April 2017, we and Bristol-Myers Squibb announced an expansion of our clinical trial collaboration to include two pivotal programs in NSCLC and head & neck cancer. Phase III trials in these additional tumor types are also expected to be initiated in 2017.

In October 2017, we and AstraZeneca announced an expansion of our clinical trial collaboration to include a Phase III trial of epacadostat in combination with AstraZeneca's PD-L1 inhibitor durvalumab in patients with Stage III NSCLC.

In June 2017, we and Roche/Genentech decided to close ECHO-110, the Phase I/II dose escalation trial of epacadostat in combination with atezolizumab, to future enrollment.

In January 2017, we licensed worldwide rights from Calithera Biosciences, Inc. to develop and commercialize INCB01158, a first-in-class, small molecule arginase inhibitor in hematology and oncology. In preclinical models, arginase inhibition has been shown to enhance anti-tumor immunity both as a single agent and in combination with other immuno-modulatory therapeutics. INCB01158 is currently being studied as a monotherapy and in combination with the anti-PD-1 agent pembrolizumab.

INCSHR1210 is an anti-PD-1 monoclonal antibody that we have licensed under our agreement with Jiangsu Hengrui Medicine Co., Ltd. (Hengrui). Many tumor cells express PD-L1, an immunosuppressive PD-1 ligand. Inhibition of the interaction between PD-1 and PD-L1, known as immune checkpoint blockade, can enhance T-cell responses and mediate preclinical antitumor activity. The dose-escalation portion of the proof-of-concept clinical trial of INCSHR1210 in patients with advanced solid tumors has been completed, revealing a side-effect profile that is different from that seen with other PD-1 inhibitors. Enrollment of new subjects into Part 2 of the Phase I trial was reinitiated in order to confirm the compound's side effect profile, and enrollment of new subjects has now been halted.

In October 2017, we and MacroGenics announced an exclusive global collaboration and license agreement for MacroGenics' MGA012, an investigational monoclonal antibody that inhibits PD-1. Upon closing, we will obtain exclusive worldwide rights for the development and commercialization of MGA012 in all indications. Enrollment in the dose escalation portion of the Phase 1 study of MGA012 has been completed and the molecule is currently being evaluated as monotherapy across four solid tumor types in the dose expansion portion of the study.

We have two co-stimulatory antibodies in clinical development. INCAGN1876 is an anti-GITR agonist antibody and INCAGN1949 is an anti-OX40 agonist antibody. Both are programs within our antibody discovery alliance with Agenus Inc. GITR and OX40 are costimulatory receptors that are expressed on effector T cells and is important for T cell survival and enhanced cytokine production. Both are also expressed on regulatory T cells and can abrogate their suppressive function. Preclinical data demonstrate that anti-GITR and anti-OX40 agonist antibodies inhibit tumor growth

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by enhancing the levels and function of effector T cells and by decreasing regulatory T cells. Clinical trials of both INCAGN1876 and INCAGN1949 were initiated in 2016, and both agents are being studied as a monotherapy and in combination with other immune checkpoint inhibitors.

We have also launched two platform studies to investigate the effects of PD-1, JAK1, IDO1 and PI3K inhibition on the tumor microenvironment. The PD-1 platform study is investigating the effects of adding either itacitinib (JAK1) or INCB50465 (PI3K) to pembrolizumab (PD-1). The JAK1 platform study is investigating all-oral doublets combining either INCB50465 (PI3K) or epacadostat (IDO1) with itacitinib (JAK1).

	Indication	Status Update
Epacadostat (IDO1)	Unresectable or metastatic, advanced melanoma	Phase III (ECHO-301) in combination with pembrolizumab (PD-1)
Epacadostat (IDO1)	NSCLC, renal, bladder, head & neck cancer	Phase III in combination with pembrolizumab (PD-1) expected to begin in 2017
Epacadostat (IDO1)	NSCLC, head & neck cancer	Phase III in combination with nivolumab (PD-1) expected to begin in 2017
Epacadostat (IDO1)	NSCLC	Phase III in combination with durvalumab (PD-L1) expected to begin in H1 2018
Epacadostat (IDO1)	Multiple tumor types	Phase II (ECHO-202) expansion cohorts in combination with pembrolizumab (PD-1)
Epacadostat (IDO1)	Multiple tumor types	Phase II (ECHO-204) expansion cohorts in combination with nivolumab (PD-1)
Epacadostat (IDO1)	Multiple tumor types	Phase II (ECHO-203) expansion cohorts in combination with durvalumab (PD-L1)
INCB01158 (ARG)1	Solid tumors	Phase I/II
INCSHR1210 (PD-1)2	Solid tumors	Phase I/II dose-escalation completed; enrollment halted
INCAGN1876 (GITR)3	Solid tumors	Phase I/II
INCAGN1949 (OX40)3	Solid tumors	Phase I/II
PD-1 platform study	Solid tumors	Phase I/II, pembrolizumab (PD-1) in combination with itacitinib (JAK1) or INCB50465 (PI3K)
JAK1 platform study	Solid tumors	Phase I/II, itacitinib (JAK1) in combination with epacadostat (IDO1) or INCB50465 (PI3K)

1. INCB01158 co-developed with Calithera

2. INCSHR1210 licensed from Hengrui

3. INCAGN1876 & INCAGN1949 from discovery alliance with Agenus

Clinical Programs outside Oncology

In January 2017, we initiated a Phase II trial of ruxolitinib cream for the topical treatment of atopic dermatitis. Atopic dermatitis is a skin disorder that causes the skin to become red, scaly, and itchy. Onset can occur at any age, but is much more common in infants and children. United States and European prevalence are estimated at 10.3 million patients and 6.5 million patients, respectively.

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A Phase II trial of topical ruxolitinib in patients with vitiligo, a long term skin condition characterized by patches of the skin losing their pigment, was initiated in June 2017.

	Indication	Status Update
Topical ruxolitinib (JAK1/JAK2)	Atopic dermatitis	Phase II (topical formulation1)
Topical ruxolitinib (JAK1/JAK2)	Vitiligo	Phase II (topical formulation1)

1. Novartis' rights for ruxolitinib outside of the United States under our Collaboration and License Agreement with Novartis do not include topical administration.

Partnered Programs

Baricitinib

We have a second JAK1 and JAK2 inhibitor, baricitinib, which is subject to our collaboration agreement with Eli Lilly and Company, in which Lilly received exclusive worldwide development and commercialization rights to the compound for inflammatory and autoimmune diseases. The Phase III program of baricitinib in patients with rheumatoid arthritis incorporated all three rheumatoid arthritis populations (methotrexate naïve, biologic naïve, and tumor necrosis factor (TNF) inhibitor inadequate responders); used event rates to fully power the baricitinib program for structural comparison and non-inferiority vs. adalimumab; and evaluated patient-reported outcomes. All four Phase III trials met their respective primary endpoints.

In January 2016, Lilly submitted a New Drug Application (NDA) to the FDA and a Marketing Authorization Application (MAA) to the European Medicines Agency for baricitinib as treatment for rheumatoid arthritis. In February 2017, we and Lilly announced that the European Commission approved baricitinib as OLUMIANT for the treatment of moderate-to-severe rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to, one or more disease-modifying antirheumatic drugs (DMARDs). In July 2017, Japan's Ministry of Health, Labor and Welfare (MHLW) granted marketing approval for OLUMIANT for the treatment of rheumatoid arthritis (including the prevention of structural injury of joints) in patients with inadequate response to standard-of-care therapies.

In April 2017, we and Lilly announced that the FDA had issued a complete response letter for the New Drug Application of baricitinib as a once-daily oral medication for the treatment of moderate-to-severe rheumatoid arthritis. The letter indicates that the FDA is unable to approve the application in its current form. Specifically, the FDA indicated that additional clinical data are needed to determine the most appropriate doses. The FDA also stated that additional data are necessary to further characterize safety concerns across treatment arms. In August 2017, we and Lilly announced that a resubmission of the NDA for baricitinib is now expected before the end of January 2018. The resubmission package will include new safety and efficacy data. The companies anticipate the FDA will classify the application as a Class II resubmission, which would start a new six-month review cycle.

Rheumatoid Arthritis. Rheumatoid arthritis is an autoimmune disease characterized by aberrant or abnormal immune mechanisms that lead to joint inflammation and swelling and, in some patients, the progressive destruction of joints. Rheumatoid arthritis can also affect connective tissue in the skin and organs of the body.

Current rheumatoid arthritis treatments include the use of non steroidal anti inflammatory drugs, disease modifying anti rheumatic drugs, such as methotrexate, and the newer biological response modifiers that target pro inflammatory cytokines, such as tumor necrosis factor, implicated in the pathogenesis of rheumatoid arthritis. None of these approaches to treatment is curative; therefore, there remains an unmet need for new safe and effective treatment options for these patients. Rheumatoid arthritis is estimated to affect about 1% of the world's population.

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Psoriatic Arthritis. Psoriatic arthritis (PsA) is an inflammatory arthritis that is seen in association with skin psoriasis. It causes joint pain and swelling that can lead to damage of the joint if the inflammation is not controlled. Baricitinib has been shown to inhibit the JAK-STAT pathway in related conditions such as psoriasis in Phase II trials, and based on its activity profile, baricitinib also has the potential to demonstrate positive clinical outcomes in PsA. Lilly expects to initiate a Phase III program to evaluate the safety and efficacy of baricitinib in patients with PsA during 2018.

Atopic Dermatitis. Atopic dermatitis (AtD) is a condition that makes the skin red and itchy and which is common in children but can occur at any age. Atopic dermatitis is long lasting and tends to flare periodically and then subside. Lilly has conducted a Phase IIa trial to evaluate the safety and efficacy of baricitinib in patients with moderate-to-severe atopic dermatitis. The JAK-STAT pathway has been shown to play an essential role in the dysregulation of immune responses in atopic dermatitis. Therefore, we believe that inhibiting cytokine pathways dependent on JAK1 and JAK2 may lead to positive clinical outcomes in atopic dermatitis. In September 2017, we and Lilly announced that Lilly plans to initiate a Phase III program to evaluate the safety and efficacy of baricitinib in patients with moderate to severe AtD.

Systemic Lupus Erythematosus. Systemic lupus erythematosus (SLE) is a chronic disease that causes inflammation. In addition to affecting the skin and joints, it can affect other organs in the body such as the kidneys, the tissue lining the lungs and heart, and the brain. Lilly has initiated a Phase II trial to evaluate the safety and efficacy of baricitinib in patients with SLE. Baricitinib's activity profile suggests that it inhibits cytokines implicated in SLE such as type I interferon (IFN), type II IFN- , IL-6, and IL-23 as well as other cytokines that may have a role in SLE, including granulocyte macrophage colony stimulating factor (GM-CSF) and IL-12. The potential impact of baricitinib on the IFN pathway is highly relevant to SLE, as clinical and preclinical studies have established that this pathway is involved in the pathogenesis of SLE.

We exercised our co-development options in both rheumatoid arthritis and psoriatic arthritis to fund 30% of future global development costs through regulatory approval, including post-launch studies required by a regulatory authority, in exchange for increased tiered royalties ranging up to the high twenties on potential future sales. We also exercised our co-development options in both atopic dermatitis and axial spondyloarthritis, should Lilly decide to progress into a pivotal program in these indications.

Capmatinib

Capmatinib is a potent and highly selective c-MET inhibitor. The investigational compound has demonstrated inhibitory activity in cell-based biochemical and functional assays that measure c-MET signaling and c-MET dependent cell proliferation, survival and migration. Under our agreement, Novartis received worldwide exclusive development and commercialization rights to capmatinib and certain back up compounds in all indications. Capmatinib is being evaluated in patients with hepatocellular carcinoma, non small cell lung cancer and other solid tumors, and may have potential utility as a combination agent.

c MET is a clinically validated receptor kinase cancer target. Abnormal c MET activation in cancer correlates with poor prognosis. Dysregulation of the c MET pathway triggers tumor growth, formation of new blood vessels that supply the tumor with nutrients, and causes cancer to spread to other organs. Dysregulation of the c MET pathway is seen in many types of cancers, including lung, kidney, liver, stomach, breast and brain.

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	Indication	Status Update
Baricitinib (JAK1/JAK2)1	Rheumatoid arthritis	Approved in Europe and Japan; CRL issued by FDA
Baricitinib (JAK1/JAK2)1	Psoriatic arthritis	Lilly expects the Phase III program to start in 2018
Baricitinib (JAK1/JAK2)1	Atopic dermatitis	Lilly expects the Phase III program to start in late 2017
Baricitinib (JAK1/JAK2)1	Systemic lupus erythematosus	Phase II
Capmatinib (c-MET)2	NSCLC, liver cancer	Phase II in EGFR wild-type ALK negative NSCLC patients with c-MET amplification and mutation

1. Baricitinib licensed to Lilly

2. Capmatinib licensed to Novartis

License Agreements and Business Relationships

As part of our business strategy, we establish business relationships, including collaborative arrangements with other companies and medical research institutions to assist in the clinical development and/or commercialization of certain of our drugs and drug candidates and to provide support for our research programs. We also evaluate opportunities for acquiring products or rights to products and technologies that are complementary to our business from other companies and medical research institutions.

Below is a brief description of our significant business relationships and collaborations and related license agreements that expand our pipeline and provide us with certain rights to existing and potential new products and technologies.

Novartis

In November 2009, we entered into a Collaboration and License Agreement with Novartis. Under the terms of the agreement, Novartis received exclusive development and commercialization rights outside of the United States to ruxolitinib and certain back up compounds for hematologic and oncology indications, including all hematological malignancies, solid tumors and myeloproliferative diseases. We retained exclusive development and commercialization rights to JAKAFI (ruxolitinib) in the United States and in certain other indications. Novartis also received worldwide exclusive development and commercialization rights to our c MET inhibitor compound capmatinib and certain back up compounds in all indications. We retained options to co develop and to co promote capmatinib in the United States.

Under this agreement, we received an upfront payment and immediate milestone payment totaling $210.0 million and were initially eligible to receive additional payments of up to approximately $1.2 billion if defined development and commercialization milestones are achieved. We are also eligible to receive tiered, double digit royalties ranging from the upper teens to the mid twenties percent on future ruxolitinib net sales outside of the United States, and tiered, worldwide royalties on future capmatinib net sales that range from 12% to 14%. In addition, Novartis has received reimbursement and pricing approval for ruxolitinib in a specified number of countries, and we are now obligated to pay to Novartis tiered royalties in the low single digits on future ruxolitinib net sales within the United States. Each company is responsible for costs relating to the development and commercialization of ruxolitinib in its respective territories, with costs of collaborative studies shared equally. Novartis is also responsible for all costs relating to the development and commercialization of capmatinib.

In April 2016, we amended this agreement to provide that Novartis has exclusive research, development and commercialization rights outside of the United States to ruxolitinib (excluding topical formulations) in the GVHD field. Under this amendment, we received a $5.0 million payment in exchange for the development and commercialization rights

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to ruxolitinib in GVHD outside of the United States and became eligible to receive up to $75.0 million of additional potential development and regulatory milestones relating to GVHD. In March 2017, we recognized a $25.0 million milestone payment for the first patient first visit in a GVHD study.

The Novartis agreement will continue on a program by program basis until Novartis has no royalty payment obligations with respect to such program or, if earlier, the termination of the agreement or any program in accordance with the terms of the agreement. Royalties are payable by Novartis on a product by product and country by country basis until the latest to occur of (1) the expiration of the last valid claim of the licensed patent rights covering the licensed product in the relevant country, (2) the expiration of regulatory exclusivity for the licensed product in such country and (3) a specified period from first commercial sale in such country of the licensed product by Novartis or its affiliates or sublicensees. The agreement may be terminated in its entirety or on a program by program basis by Novartis for convenience. The agreement may also be terminated by either party under certain other circumstances, including material breach.

Lilly

In December 2009, we entered into a License, Development and Commercialization Agreement with Lilly. Under the terms of the agreement, Lilly received exclusive worldwide development and commercialization rights to baricitinib and certain back up compounds for inflammatory and autoimmune diseases. We received an initial payment of $90.0 million, and were initially eligible to receive additional payments of up to $665.0 million based on the achievement of defined development, regulatory and commercialization milestones.

We retained options to co-develop our JAK1/JAK2 inhibitors with Lilly on a compound-by-compound and indication-by-indication basis. Lilly is responsible for all costs relating to the development and commercialization of the compounds unless we elect to co-develop any compounds or indications. If we elect to co-develop any compounds and/or indications, we would be responsible for funding 30% of the associated future global development costs from the initiation of a Phase IIb trial through regulatory approval, including post-launch studies required by a regulatory authority. We would receive an incremental royalty rate increase across all tiers resulting in effective royalty rates ranging up to the high twenties on potential future global net sales for compounds and/or indications that we elect to co-develop. For indications that we elect not to co-develop, we would receive tiered, double-digit royalty payments on future global net sales with rates ranging up to 20% if the product is successfully commercialized. We previously had retained an option to co-promote products in the United States but, in March 2016, we waived our co-promotion option as part of an amendment to the agreement.

In July 2010, we elected to co-develop baricitinib with Lilly in rheumatoid arthritis and we are responsible for funding 30% of the associated future global development costs for this indication from the initiation of the Phase IIb trial through regulatory approval, including post-launch studies required by a regulatory authority. In January 2017, we elected to co-develop baricitinib with Lilly in psoriatic arthritis. We also exercised our co-development options in both atopic dermatitis and axial spondyloarthritis, should Lilly decide to progress into a pivotal program in these indications.

In March 2016, we entered into an amendment to the agreement with Lilly that allows us to engage in the development and commercialization of ruxolitinib in the GVHD field. We paid Lilly an upfront payment of $35.0 million and Lilly is eligible to receive up to $40.0 million in additional regulatory milestone payments relating to ruxolitinib in the GVHD field.

In February 2017, the European Commission announced the approval of baricitinib as OLUMIANT, triggering a $65.0 million milestone payment from Lilly. In July 2017, Japan's MHLW granted marketing approval for OLUMIANT, triggering a $15.0 million milestone payment to Incyte from Lilly.

The Lilly agreement will continue until Lilly no longer has any royalty payment obligations or, if earlier, the termination of the agreement in accordance with its terms. Royalties are payable by Lilly on a product by product and country by country basis until the latest to occur of (1) the expiration of the last valid claim of the licensed patent rights covering the licensed product in the relevant country, (2) the expiration of regulatory exclusivity for the licensed product in such country and (3) a specified period from first commercial sale in such country of the licensed product by Lilly or its affiliates or sublicensees. The agreement may be terminated by Lilly for convenience, and may also be terminated under certain other circumstances, including material breach.

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Agenus

In January 2015, we entered into a License, Development and Commercialization Agreement with Agenus Inc. and its wholly-owned subsidiary, 4-Antibody AG (now known as Agenus Switzerland Inc.), which we collectively refer to as Agenus. Under this agreement, the parties have agreed to collaborate on the discovery of novel immuno-therapeutics using Agenus' antibody discovery platforms. In February 2017, we and Agenus amended this agreement.

Under the terms of this agreement, as amended, we received exclusive worldwide development and commercialization rights to four checkpoint modulators directed against GITR, OX40, LAG-3 and TIM-3. In addition to the initial four program targets, we and Agenus have the option to jointly nominate and pursue additional targets within the framework of the collaboration, and in November 2015, three more targets were added. Targets may be designated profit-share programs, where all costs and profits are shared equally by us and Agenus, or royalty-bearing programs, where we are responsible for all costs associated with discovery, preclinical, clinical development and commercialization activities. The programs relating to GITR and OX40 and two of the undisclosed targets were profit-share programs until February 2017, while the other targets currently under collaboration are royalty-bearing programs. The February 2017 amendment converted the programs relating to GITR and OX40 to royalty-bearing programs and removed from the collaboration the profit-share programs relating to the two undisclosed targets, with one reverting to us and one reverting to Agenus. Should any of those removed programs be successfully developed by a party, the other party will be eligible to receive the same milestone payments as the royalty-bearing programs and royalties at a 15% rate on global net sales. There are currently no profit-share programs. For each royalty-bearing product other than GITR and OX40, Agenus will be eligible to receive tiered royalties on global net sales ranging from 6% to 12%. For GITR and OX40, Agenus will be eligible to receive 15% royalties on global net sales. Under the February 2017 amendment, we paid Agenus $20.0 million in accelerated milestones relating to the clinical development of the GITR and OX40 programs. Agenus is eligible to receive up to an additional $510.0 million in future contingent development, regulatory and commercialization milestones across all programs in the collaboration. The agreement may be terminated by us for convenience upon 12 months' notice and may also be terminated under certain other circumstances, including material breach.

Hengrui

In September 2015, we entered into a License and Collaboration Agreement with Hengrui. Under the terms of this agreement, we received exclusive development and commercialization rights worldwide, with the exception of Mainland China, Hong Kong, Macau and Taiwan, to INCSHR1210, an investigational PD-1 monoclonal antibody, and certain back-up compounds. We paid to Hengrui an upfront payment of $25.0 million. Hengrui is also eligible to receive potential milestone payments of up to $770.0 million, consisting of $90.0 million for regulatory approval milestones, $530.0 million for commercial performance milestones, and $150.0 million for a clinical superiority milestone. Also, Hengrui may be eligible to receive tiered royalties in the high single digits to mid-double digits based on net sales in our territories. Each company will be responsible for costs relating to the development and commercialization of the PD-1 monoclonal antibody in its respective territories.

The agreement will continue on a country-by-country basis until we have no royalty payment obligations with respect to such country or, if earlier, the termination of the agreement in accordance with its terms. The agreement may be terminated in its entirety by us for convenience, and may also be terminated under certain other circumstances, including material breach.

Merus

In December 2016, we entered into a Collaboration and License Agreement with Merus N.V. Under this agreement, which became effective in January 2017, the parties have agreed to collaborate with respect to the research, discovery

and development of bispecific antibodies utilizing Merus' technology platform. The collaboration encompasses up to eleven independent programs, including two of Merus' current preclinical immuno-oncology discovery programs. We received exclusive development and commercialization rights outside of the United States to products and product candidates resulting from one of Merus' current preclinical discovery programs, referred to as "Program 1." We also received worldwide exclusive development and commercialization rights to products and product candidates resulting from the other current Merus preclinical discovery program that is subject to the collaboration and to up to nine additional

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programs. Merus retained exclusive development and commercialization rights in the United States to products and product candidates resulting from Program 1 and options, subject to certain conditions, to co-fund development of products resulting from two other programs in exchange for a share of profits in the United States. Merus will also have the right to participate in a specified proportion of detailing activities in the United States for one of those co-developed programs. Should Program 1 fail to successfully complete IND-enabling toxicology studies, Merus would be granted an additional option to co-fund development of a program in exchange for a share of profits in the United States. All costs related to the collaboration are subject to joint research and development plans. Each party will share equally the costs of mutually agreed global development activities for Program 1, and fund itself any independent development activities in its territory. We will be responsible for all research, development and commercialization costs relating to all other programs, subject to Merus' election to co-fund development and co-detail described above. If Merus exercises its co-funding option for a program, Merus would be responsible for funding 35% of the associated future global development costs and, for certain of such programs, would be responsible for reimbursing us for certain development costs incurred prior to the option exercise. All products as to which Merus has exercised its option to co-fund development would be subject to joint development plans and overseen by a joint development committee, but we will have final determination as to such plans in cases of dispute.

In February 2017, we paid Merus an upfront non-refundable payment of $120.0 million. For each program as to which Merus does not have commercialization or co-development rights, Merus will be eligible to receive up to $100.0 million in future contingent development and regulatory milestones and up to $250.0 million in commercialization milestones as well as tiered royalties ranging from 6% to 10% of global net sales. For each program as to which Merus exercises its option to co-fund development, Merus will be eligible to receive a 50% share of profits (or sustain 50% of any losses) in the United States and be eligible to receive tiered royalties ranging from 6% to 10% of net sales of products outside of the United States. If Merus opts to cease co-funding a program as to which it exercised its co-development option, then Merus will no longer receive a share of profits in the United States but will be eligible to receive the same milestones from the co-funding termination date and the same tiered royalties described above with respect to non-co-developed programs and, depending on the stage at which Merus chose to cease co-funding development costs, additional royalties ranging up to 4% of net sales in the United States. For Program 1, we and Merus will each be eligible to receive tiered royalties on net sales in the other party's territory at rates ranging from 6% to 10%.

The Merus agreement will continue on a program-by-program basis until we have no royalty payment obligations with respect to such program or, if earlier, the termination of the agreement or any program in accordance with the terms of the agreement. The agreement may be terminated in its entirety or on a program-by-program basis by us for convenience. The agreement may also be terminated by either party under certain other circumstances, including material breach, as set forth in the agreement. If the agreement is terminated with respect to one or more programs, all rights in the terminated programs revert to Merus, subject to payment to us of a reverse royalty of up to 4% on sales of future products, if Merus elects to pursue development and commercialization of products arising from the terminated programs.

Calithera

In January 2017, we entered into a Collaboration and License Agreement with Calithera Biosciences, Inc. Under this agreement, we received an exclusive, worldwide license to develop and commercialize small molecule arginase inhibitors, including INCB01158 (CB-1158), which is currently in phase I clinical trials, for hematology and oncology indications. We have agreed to co-fund 70% of the global development costs for the development of the licensed products for hematology and oncology indications. Calithera will have the right to conduct certain clinical development under the collaboration, including combination studies of a licensed product with a proprietary compound of Calithera. We will be entitled to 60% of the profits and losses from net sales of licensed product in the United States, and Calithera will have the right to co-detail licensed products in the United States, and we have agreed

to pay Calithera tiered royalties ranging from the low to mid-double digits on net sales of licensed products outside the United States. Calithera may opt out of its co-funding obligation, in which case the U.S. profit sharing will no longer be in effect, and we have agreed to pay Calithera tiered royalties ranging from the low to mid-double digits on net sales of licensed products both in the United States and outside the United States, and additional royalties to reimburse Calithera for previously incurred development costs.

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Calithera retains rights to certain arginase inhibitors that are not part of the collaboration for specific orphan indications outside of hematology and oncology, subject to our rights to negotiate a license for any such programs under specified circumstances if Calithera elects to out-license them.

In January 2017, we paid Calithera an upfront license fee of $45.0 million and have agreed to pay potential development, regulatory and sales milestone payments of over $430.0 million if the profit share is in effect, or $750.0 million if the profit share terminates.

The Calithera agreement will continue on a product-by-product and country-by-country basis for so long as we are developing or commercializing products in the United States (if the parties are sharing profits in the United States) and until we have no further royalty payment obligations, unless earlier terminated according to the terms of the agreement. The agreement may be terminated in its entirety or on a product-by-product and/or a country-by-country basis by us for convenience. The agreement may also be terminated by us for Calithera's uncured material breach, by Calithera for our uncured material breach and by either party for bankruptcy or patent challenge. If the agreement is terminated early with respect to one or more products or countries, all rights in the terminated products and countries revert to Calithera.

MacroGenics

In October 2017, we and MacroGenics announced an exclusive global collaboration and license agreement for MacroGenics' MGA012, an investigational monoclonal antibody that inhibits PD-1. We have obtained exclusive worldwide rights for the development and commercialization of MGA012 in all indications, while MacroGenics retains the right to develop its pipeline assets in combination with MGA012. Upon closing, we will pay MacroGenics an upfront payment of $150.0 million. MacroGenics will also be eligible to receive up to $420.0 million in potential development and regulatory milestones, and up to $330.0 million in potential commercial milestones. If MGA012 is approved and commercialized, MacroGenics would be eligible to receive royalties, tiered from 15 percent to 24 percent, on future sales of MGA012.

We will lead global development of MGA012. MacroGenics retains the right to develop its pipeline assets in combination with MGA012, and we will commercialize MGA012 with MacroGenics commercializing its asset(s), if any such potential combinations are approved. In addition, MacroGenics retains the right to manufacture a portion of both companies' global clinical and commercial supply needs of MGA012. MacroGenics intends to utilize its commercial-scale GMP facility, which is expected to be fully operational in 2018.

The transaction is expected to close in the fourth quarter of 2017, subject to the early termination or expiration of any applicable waiting periods under the Hart-Scott Rodino Act and customary closing conditions.

ARIAD Pharmaceuticals (Luxembourg) S.à.r.l. Acquisition

In June 2016, we acquired from ARIAD all of the outstanding shares of ARIAD Pharmaceuticals (Luxembourg) S.à.r.l., the parent company of ARIAD's European subsidiaries responsible for the development and commercialization of ICLUSIG in the European Union and other countries, including Switzerland, Norway, Turkey, Israel and Russia, in exchange for an upfront payment of $147.5 million, including customary working capital adjustments. We obtained an exclusive license to develop and commercialize ICLUSIG in Europe and other select countries. ARIAD will be eligible to receive from us tiered royalties on net sales of ICLUSIG in our territory and up to $135.0 million in potential future oncology development and regulatory approval milestone payments, together with additional milestone payments for non-oncology indications, if approved, in our territory.

Our license agreement with ARIAD contained a limited buy-back option for the acquirer of ARIAD to reacquire the rights to ICLUSIG. Takeda Pharmaceutical Company Limited acquired ARIAD in February 2017 but did not exercise that option, and it has now lapsed.

Critical Accounting Policies and Significant Estimates

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The preparation of financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosures of contingent assets and liabilities. On an on-going basis, we evaluate our estimates. We base our estimates on historical experience and various other assumptions that we believe to be reasonable under the circumstances, the results of which form our basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from those estimates under different assumptions or conditions.

We believe the following critical accounting policies affect the more significant judgments and estimates used in the preparation of our condensed consolidated financial statements:

- Revenue recognition;
- Research and development costs;
- Stock compensation;
- Convertible debt accounting;
- Income taxes;
- Business combinations; and
- Contingent consideration.

Revenue Recognition. Revenues are recognized when (1) persuasive evidence of an arrangement exists, (2) delivery has occurred or services have been rendered, (3) the price is fixed or determinable and (4) collectability is reasonably assured. Revenues are deferred for fees received before earned or until no further obligations exist. We exercise judgment in determining that collectability is reasonably assured or that services have been delivered in accordance with the arrangement. We assess whether the fee is fixed or determinable based on the payment terms associated with the transaction and whether the sales price is subject to refund or adjustment. We assess collectability based primarily on the customer's payment history and on the creditworthiness of the customer.

Product Revenues

Our product revenues consist of U.S. sales of JAKAFI and European sales of ICLUSIG. Product revenues are recognized once we meet all four revenue recognition criteria described above. In November 2011, we began shipping JAKAFI to our customers in the U.S., which include specialty pharmacies and wholesalers. In June 2016, we acquired the right to and began shipping ICLUSIG to our customers in the European Union and certain other jurisdictions, which include retail pharmacies, hospital pharmacies and distributors.

We recognize revenues for product received by our customers net of allowances for customer credits, including estimated rebates, chargebacks, discounts, returns, distribution service fees, patient assistance programs, and government rebates, such as Medicare Part D coverage gap reimbursements in the U.S. Product shipping and handling costs are included in cost of product revenues.

Customer Credits: Our customers are offered various forms of consideration, including allowances, service fees and prompt payment discounts. We expect our customers will earn prompt payment discounts and, therefore, we deduct the full amount of these discounts from total product sales when revenues are recognized. Service fees are also deducted from total product sales as they are earned.

Rebates and Discounts: Allowances for rebates include mandated discounts under the Medicaid Drug Rebate Program in the U.S. and mandated discounts in Europe in markets where government-sponsored healthcare systems are the primary payers for healthcare. Rebate amounts are based upon contractual agreements or legal requirements with public

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sector benefit providers. Rebates are amounts owed after the final dispensing of the product to a benefit plan participant and are based upon contractual agreements or legal requirements with public sector benefit providers. The accrual for rebates is based on statutory discount rates and expected utilization as well as historical data we have accumulated since product launch. Our estimates for expected utilization of rebates are based on data received from our customers. Rebates are generally invoiced and paid in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's activity, plus an accrual balance for known prior quarters' unpaid rebates. If actual future rebates vary from estimates, we may need to adjust prior period accruals, which would affect revenue in the period of adjustment.

Chargebacks: Chargebacks are discounts that occur when certain contracted customers, which currently consist primarily of group purchasing organizations, Public Health Service institutions, non-profit clinics, and Federal government entities purchasing via the Federal Supply Schedule, purchase directly from our wholesalers. Contracted customers generally purchase the product at a discounted price. The wholesalers, in turn, charges back to us the difference between the price initially paid by the wholesalers and the discounted price paid by the contracted customers. In addition to actual chargebacks received, we maintain an accrual for chargebacks based on the estimated contractual discounts on the inventory levels on hand in our distribution channel. If actual future chargebacks vary from these estimates, we may need to adjust prior period accruals, which would affect revenue in the period of adjustment.

Medicare Part D Coverage Gap: Medicare Part D prescription drug benefit mandates manufacturers to fund 50% of the Medicare Part D insurance coverage gap for prescription drugs sold to eligible patients. Our estimates for the expected Medicare Part D coverage gap are based on historical invoices received and in part from data received from our customers. Funding of the coverage gap is generally invoiced and paid in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's activity, plus an accrual balance for known prior quarters. If actual future funding varies from estimates, we may need to adjust prior period accruals, which would affect revenue in the period of adjustment.

Co-payment Assistance: Patients who have commercial insurance and meet certain eligibility requirements may receive co-payment assistance. We accrue a liability for co-payment assistance based on actual program participation and estimates of program redemption using data provided by third-party administrators.

Product Royalty Revenues

Royalty revenues on commercial sales for JAKAVI by Novartis are estimated based on information provided by Novartis. Royalty revenues on commercial sales for OLUMIANT by Lilly are estimated based on information provided by Lilly. We exercise judgment in determining whether the information provided is sufficiently reliable for us to base our royalty revenue recognition thereon. If actual royalties vary from estimates, we may need to adjust the prior period, which would affect royalty revenue in the period of adjustment.

Cost of Product Revenues

Cost of product revenues includes all JAKAFI related product costs as well as ICLUSIG related product costs. The ICLUSIG inventories were recorded at fair value less costs to sell in connection with the Acquisition, which resulted in a higher cost of ICLUSIG product revenues over a one year period from the acquisition date. In addition, cost of product revenues include low single digit royalties under our collaboration and license agreement to Novartis on all future sales of JAKAFI in the United States. Subsequent to the Acquisition on June 1, 2016, cost of product revenues also includes the amortization of our licensed intellectual property for ICLUSIG using the straight-line method over the estimated useful life of 12.5 years.

Contract and License Revenues

Under agreements involving multiple deliverables, services and/or rights to use assets that we entered into prior to January 1, 2011, the multiple elements are divided into separate units of accounting when certain criteria are met, including whether the delivered items have stand-alone value to the customer and whether there is objective and reliable evidence of the fair value of the undelivered items. When separate units of accounting exist, consideration is allocated

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among the separate elements based on their respective fair values. The determination of fair value of each element is based on objective evidence from historical sales of the individual elements by us to other customers. If such evidence of fair value for each undelivered element of the arrangement does not exist, all revenue from the arrangement is deferred until such time that evidence of fair value for each undelivered element does exist or until all elements of the arrangement are delivered. When elements are specifically tied to a separate earnings process, revenue is recognized when the specific performance obligation tied to the element is completed. When revenues for an element are not specifically tied to a separate earnings process, they are recognized ratably over the term of the agreement. We assess whether a substantive milestone exists at the inception of our agreements. For all milestones within our arrangements that are considered substantive, we recognize revenue upon the achievement of the associated milestone. If a milestone is not considered substantive, we would recognize the applicable milestone payment over the remaining period of performance under the arrangement. As of September 30, 2017, all remaining potential milestones under our collaborative arrangements are considered substantive.

On January 1, 2011, updated guidance on the recognition of revenues for agreements with multiple deliverables became effective and applies to any agreements we may enter into on or after January 1, 2011. This updated guidance (i) relates to whether multiple deliverables exist, how the deliverables in a revenue arrangement should be separated and how the consideration should be allocated; (ii) requires companies to allocate revenues in an arrangement using estimated selling prices of deliverables if a vendor does not have vendor-specific objective evidence or third-party evidence of selling price; and (iii) eliminates the use of the residual method and requires companies to allocate revenues using the relative selling price method. During the three and nine months ended September 30, 2017 and 2016, we did not enter into any agreements that are subject to this updated guidance. If we enter into an agreement with multiple deliverables after January 1, 2011 or amend existing agreements, this updated guidance could have a material effect on our financial statements.

Our collaborations often include contractual milestones, which typically relate to the achievement of pre-specified development, regulatory and commercialization events. These three categories of milestone events reflect the three stages of the life-cycle of our drugs, which we describe in more detail in the following paragraphs.

The regulatory review and approval process, which includes preclinical testing and clinical trials of each drug candidate, is lengthy, expensive and uncertain. Securing approval by the U.S. Food and Drug Administration (FDA) requires the submission of extensive preclinical and clinical data and supporting information to the FDA for each indication to establish a drug candidate’s safety and efficacy. The approval process takes many years, requires the expenditure of substantial resources, involves post-marketing surveillance and may involve ongoing requirements for post-marketing studies. Before commencing clinical investigations of a drug candidate in humans, we must submit an Investigational New Drug application (IND), which must be reviewed by the FDA.

The steps generally required before a drug may be marketed in the United States include preclinical laboratory tests, animal studies and formulation studies, submission to the FDA of an IND for human clinical testing, performance of adequate and well-controlled clinical trials in three phases, as described below, to establish the safety and efficacy of the drug for each indication, submission of a new drug application (NDA) or biologics license application (BLA) to the FDA for review and FDA approval of the NDA or BLA.

Similar requirements exist within foreign regulatory agencies as well. The time required satisfying the FDA requirements or similar requirements of foreign regulatory agencies may vary substantially based on the type, complexity and novelty of the product or the targeted disease.

Preclinical testing includes laboratory evaluation of product pharmacology, drug metabolism, and toxicity, which includes animal studies, to assess potential safety and efficacy as well as product chemistry, stability, formulation, development, and testing. The results of the preclinical tests, together with manufacturing information and analytical

data, are submitted to the FDA as part of an IND. The FDA may raise safety concerns or questions about the conduct of the clinical trials included in the IND, and any of these concerns or questions must be resolved before clinical trials can proceed. We cannot be sure that submission of an IND will result in the FDA allowing clinical trials to commence. Clinical trials involve the administration of the investigational drug or the marketed drug to human subjects under the supervision of qualified investigators and in accordance with good clinical practices regulations covering the protection of human

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subjects. Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. Phase I usually involves the initial introduction of the investigational drug into healthy volunteers to evaluate its safety, dosage tolerance, absorption, metabolism, distribution and excretion. Phase II usually involves clinical trials in a limited patient population to evaluate dosage tolerance and optimal dosage, identify possible adverse effects and safety risks, and evaluate and gain preliminary evidence of the efficacy of the drug for specific indications. Phase III clinical trials usually further evaluate clinical efficacy and safety by testing the drug in its final form in an expanded patient population, providing statistical evidence of efficacy and safety, and providing an adequate basis for labeling. We cannot guarantee that Phase I, Phase II or Phase III testing will be completed successfully within any specified period of time, if at all. Furthermore, we, the institutional review board for a trial, or the FDA may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

Generally, the milestone events contained in our collaboration agreements coincide with the progression of our drugs from development, to regulatory approval and then to commercialization. The process of successfully discovering a new development candidate, having it approved and successfully commercialized is highly uncertain. As such, the milestone payments we may earn from our partners involve a significant degree of risk to achieve. Therefore, as a drug candidate progresses through the stages of its life-cycle, the value of the drug candidate generally increases.

Research and Development Costs. Our policy is to expense research and development costs as incurred. We often contract with clinical research organizations (CROs) to facilitate, coordinate and perform agreed upon research and development of a new drug. To ensure that research and development costs are expensed as incurred, we record monthly accruals for clinical trials and preclinical testing costs based on the work performed under the contract.

These CRO contracts typically call for the payment of fees for services at the initiation of the contract and/or upon the achievement of certain clinical trial milestones. In the event that we prepay CRO fees, we record the prepayment as a prepaid asset and amortize the asset into research and development expense over the period of time the contracted research and development services are performed. Most professional fees, including project and clinical management, data management, monitoring, and medical writing fees are incurred throughout the contract period. These professional fees are expensed based on their percentage of completion at a particular date. Our CRO contracts generally include pass through fees. Pass through fees include, but are not limited to, regulatory expenses, investigator fees, travel costs, and other miscellaneous costs, including shipping and printing fees. We expense the costs of pass through fees under our CRO contracts as they are incurred, based on the best information available to us at the time. The estimates of the pass through fees incurred are based on the amount of work completed for the clinical trial and are monitored through correspondence with the CROs, internal reviews and a review of contractual terms. The factors utilized to derive the estimates include the number of patients enrolled, duration of the clinical trial, estimated patient attrition, screening rate and length of the dosing regimen. CRO fees incurred to set up the clinical trial are expensed during the setup period.

Under our clinical trial collaboration agreements, we may be reimbursed for certain development costs incurred. Such costs are recorded as a reduction of research and development expense in the period in which the related expense is incurred.

Stock Compensation. Share-based payment transactions with employees, which include stock options, restricted stock units (“RSUs”) and performance shares (“PSUs”), are recognized as compensation expense over the requisite service period based on their estimated fair values as well as expected forfeiture rates. The stock compensation process requires significant judgment and the use of estimates, particularly surrounding Black-Scholes assumptions such as stock price volatility over the option term and expected option lives, as well as expected forfeiture rates and the probability of PSUs vesting. The fair value of stock options, which are subject to graded vesting, are recognized as compensation expense over the requisite service period using the accelerated attribution method. The fair value of

RSUs that are subject to cliff vesting are recognized as compensation expense over the requisite service period using the straight line attribution method, and the fair value of RSUs that are subject to graded vesting are recognized as compensation expense over the requisite service period using the accelerated attribution method. The fair value of PSUs are recognized as compensation expense beginning at the time in which the performance conditions are deemed probable of achievement, over the remaining requisite service period. We recorded $34.9 million and $99.3 million of stock compensation expense for the three and nine months ended September 30, 2017, respectively. We recorded $26.5 million and $68.6 million of stock compensation expense for the three and nine months ended September 30, 2016, respectively.

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Convertible Debt Accounting. We perform an assessment of all embedded features of a debt instrument to determine if (1) such features should be bifurcated and separately accounted for, and (2) if bifurcation requirements are met, whether such features should be classified and accounted for as equity or liability instruments. If the embedded feature meets the requirements to be bifurcated and accounted for as a liability, the fair value of the embedded feature is measured initially, included as a liability on the condensed consolidated balance sheets, and re-measured to fair value at each reporting period. Any changes in fair value are recorded in the condensed consolidated statement of operations. We monitor, on an ongoing basis, whether events or circumstances could give rise to a change in our classification of embedded features.

We determined the embedded conversion options in the 0.375% convertible senior notes due 2018 (the 2018 Notes) and the 1.25% convertible senior notes due 2020 (the 2020 Notes) are not required to be separately accounted for as derivatives. However, since the 2018 Notes and the 2020 Notes can be settled in cash or common shares or a combination of cash and common shares at our option, we are required to separate the 2018 Notes and 2020 Notes into a liability and equity component. The carrying amount of the liability component is calculated by measuring the fair value of a similar liability that does not have an associated equity component. The carrying amount of the equity component representing the embedded conversion option is determined by deducting the fair value of the liability component from the initial proceeds. The excess of the principal amount of the liability component over its carrying amount is amortized to interest expense over the expected life of the 2018 Notes and 2020 Notes using the effective interest method. The equity component is not re-measured as long as it continues to meet the conditions for equity classification for contracts in an entity’s own equity.

The fair value of the liability component of the 2018 Notes was estimated at $299.4 million at issuance. Therefore, the difference between the $375.0 million face value of the 2018 Notes at issuance and the $299.4 million estimated fair value of the liability component will be amortized to interest expense over the term of the 2018 Notes through November 15, 2018 using the effective interest method.

The fair value of the liability component of the 2020 Notes was estimated at $274.8 million at issuance. Therefore, the difference between the $375.0 million face value of the 2020 Notes at issuance and the $274.8 million estimated fair value of the liability component will be amortized to interest expense over the term of the 2020 Notes through November 15, 2020 using the effective interest method.

The estimated fair value of the liability components at the date of issuance for the 2018 Notes and 2020 Notes were determined using valuation models and are complex and subject to judgment. Significant assumptions within the valuation models included an implied credit spread, the expected volatility and dividend yield of our common stock and the risk free interest rate for notes with a similar term.

Prior to May 14, 2014, the 2018 Notes and 2020 Notes were not convertible except in connection with a make-whole fundamental change, as defined in the respective indentures. Beginning on, and including, May 15, 2014, the 2018 Notes and 2020 Notes are convertible prior to the close of business on the business day immediately preceding May 15, 2018, in the case of the 2018 Notes, and May 15, 2020, in the case of the 2020 Notes, only under the following circumstances: (1) during any calendar quarter commencing after the calendar quarter ending on March 31, 2014 (and only during such calendar quarter), if the last reported sale price of our common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price for the 2018 Notes or 2020 Notes, as applicable, on each applicable trading day; (2) during the five business day period after any five consecutive trading day period (the measurement period) in which the trading price per $1,000 principal amount of 2018 Notes or 2020 Notes, as applicable, for each trading day of the measurement period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate for the 2018 Notes or 2020 Notes, as applicable, on each such trading day; or (3) upon the occurrence of specified corporate events. On or after May 15,

2018, in the case of the 2018 Notes, and May 15, 2020, in the case of the 2020 Notes, until the close of business on the second scheduled trading day immediately preceding the relevant maturity date, the Notes are convertible at any time, regardless of the foregoing circumstances. Upon conversion we will pay or deliver, as the case may be, cash, shares of common stock or a combination of cash and shares of common stock, at our election.

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Upon an induced conversion, we allocate the fair value of the consideration transferred to the convertible debt holder to the liability component equal to the fair value of the liability immediately before extinguishment. The difference between the consideration allocated to the liability component and the net carrying amount of the liability component is recorded as expense related to senior note conversions.

On a quarterly basis, we perform an assessment in order to determine whether the 2018 Notes or 2020 Notes have become convertible at the option of the holder, based on meeting any of the conversion criteria described above. Should either the 2018 Notes or the 2020 Notes become convertible, we then assess our intent and ability to settle the 2018 Notes or the 2020 Notes in cash, shares of common stock, or a combination of cash and shares of common stock, in order to determine the appropriate classification of the 2018 Notes and the 2020 Notes at the balance sheet date. On October 1, 2017, the 2018 Notes and 2020 Notes became convertible through at least December 31, 2017, based on meeting the conversion criteria related to the sale price of our common stock during the calendar quarter ended September 30, 2017 as described above. Management's intent is to settle any conversions of 2018 Notes or 2020 Notes in common shares and, therefore, the 2018 and 2020 Notes are reflected in long term liabilities on the condensed consolidated balance sheet as of September 30, 2017.

Income Taxes. We account for income taxes using an asset and liability approach to financial accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement carrying amounts and tax bases of assets and liabilities using enacted tax rates in effect for years in which the basis differences are expected to reverse. We periodically assess the likelihood of the realization of deferred tax assets, and reduce the carrying amount of these deferred tax assets to an amount that is considered to be more-likely-than-not realizable. Our assessment considers recent cumulative earnings experience, projections of future taxable income (losses) and ongoing prudent and feasible tax planning strategies. When performing our assessment on projections of future taxable income (losses), we consider factors such as the likelihood of regulatory approval and commercial success of products currently under development, among other factors. Significant judgment is required in making this assessment and, to the extent that a reversal of any portion of our valuation allowance against our deferred tax assets is deemed appropriate, a tax benefit will be recognized against our income tax provision in the period of such reversal.

We do not recognize a tax benefit for an uncertain tax position unless it is more-likely-than-not that the position will be sustained upon examination based on the technical merits of the position. The tax benefit that is recorded for these positions is measured at the largest amount of benefit that is greater than 50 percent likely of being realized upon ultimate settlement. We adjust the level of the liability to reflect any subsequent changes in the relevant facts surrounding the uncertain positions. Any interest and penalties on uncertain tax positions are included within the tax provision.

Business combinations. Acquired businesses are accounted for using the acquisition method of accounting, which requires that assets acquired and liabilities assumed be recorded at fair value, with limited exceptions. Any excess of the purchase price over the fair value of the net assets acquired is recorded as goodwill. Transaction costs are expensed as incurred. The operating results of the acquired business are reflected in our consolidated financial statements after the date of acquisition. Acquired in-process research and development ("IPR&D") is recognized at fair value and initially characterized as an indefinite-lived intangible asset, irrespective of whether the acquired IPR&D has an alternative future use. When the related research and development is completed, the asset will be assigned a useful life and amortized. Acquired intellectual property rights are recognized at fair value and amortized over the estimated useful life.

The fair value of an IPR&D intangible asset acquired in the Acquisition was determined using an income approach. The assumptions used to estimate the cash flows of the IPR&D (which relates to the potential approval of ICLUSIG as a second line treatment) included a probability of technical success ("PTS") of 25%, discount rate of 16%, estimated

gross margins of 98%, income tax rates ranging from 7.8% in periods in which we have established tax holidays to 13.8% thereafter, and operating expenses consisting of direct costs based on the anticipated level of revenues as well as probability weighted milestone payments estimated for 2020 related to the clinical results and potential approval of ICLUSIG in second line.

The fair value of licensed intellectual property rights acquired in the Acquisition was determined using an income approach. The assumptions used to estimate the cash flows of the licensed intellectual property from the Acquisition included a discount rate of 15%, estimated gross margins of 98%, income tax rates ranging from 7.8% in periods in which

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we have established tax holidays to 13.8% thereafter, and operating expenses consisting of direct costs based on the anticipated level of revenues as well as the $7.0 million of research and development cost sharing payments we have agreed to fund in 2016 and 2017.

Indefinite-lived intangible assets, including IPR&D, are tested for impairment annually or more frequently if events or changes in circumstances between annual tests indicate that the asset may be impaired. Impairment losses on indefinite-lived intangible assets are recognized based solely on a comparison of the fair value of the asset to its carrying value. Due to the discontinuation of the OPTIC-2L study, we considered our indefinite-lived IPR&D asset to be impaired and recorded $12.0 million of research and development expense on the condensed consolidated statements of operations during the three and nine months ended September 30, 2017.

Long-lived assets, including licensed intellectual property rights, with finite lives are tested for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. If indicators of impairment are present, the asset is tested for recoverability by comparing the carrying value of the asset to the related estimated undiscounted future cash flows expected to be derived from the asset. If the expected cash flows are less than the carrying value of the asset, then the asset is considered to be impaired and its carrying value is written down to fair value, based on the related estimated discounted future cash flows.

Goodwill is calculated as the difference between the acquisition date fair value of the consideration transferred and the values assigned to the assets acquired and liabilities assumed. Goodwill is not amortized but is tested for impairment at least annually at the reporting unit level. A reporting unit is the same as, or one level below, an operating segment. Our operations are currently comprised of a single, entity wide reporting unit.

Acquisition-related contingent consideration. Acquisition-related contingent consideration, which consists of our future royalty and certain potential milestone obligations to ARIAD, is recorded on the acquisition date at the estimated fair value of the obligation, in accordance with the acquisition method of accounting. The fair value measurement is based on significant inputs that are unobservable in the market and thus represents a Level 3 measurement.

The preliminary fair value of contingent consideration was determined using an income approach based on estimated ICLUSIG revenues in our licensed territory for both the approved third line treatment, as well as the second line treatment that until the three months ended September 30, 2017 was under development. The PTS of the second line indication was estimated at 25% based on the early stage of development and competitive market landscape, and the estimated future cash flows for the second line indication were probability weighted accordingly. The total projected cash flows of the third line and second line indications were estimated over 18 years, and discounted to present value using a discount rate of 10%. In addition, based on the believed limited effectiveness of ICLUSIG beyond the existing oncology indications, the fact that no development is currently ongoing for any new oncology or any non-oncology indications, and the lack of intention by us and ARIAD to develop ICLUSIG in additional oncology or non-oncology indications, the fair value of any cash flows for any new oncology or non-oncology was determined to be nil.

The fair value of the acquisition-related contingent consideration is remeasured each reporting period, with changes in fair value recorded in the consolidated statements of operations. Changes in the fair value of the acquisition-related contingent consideration can result from changes to one or multiple inputs including projected revenues, discount rates and the PTS of the second line indication for ICLUSIG, and a benefit of $24.0 million was recorded during the three and nine months ended September 30, 2017 related to the lack of expected future sales royalties payable due to the discontinued OPTIC-2L clinical trial for the second line indication for ICLUSIG. These inputs are analyzed on a quarterly basis as changes to the inputs could have a material impact on the amount of acquisition-related contingent consideration recorded during the reporting period.

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," which will replace numerous requirements in U.S. GAAP, including industry-specific requirements. This guidance provides a five step model to be applied to all contracts with customers, with an underlying principle that an entity will recognize revenue to depict the transfer of goods or services to

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customers at an amount that the entity expects to be entitled to in exchange for those goods or services. ASC No. 2014-09 requires extensive quantitative and qualitative disclosures covering the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including disclosures on significant judgments made when applying the guidance. This guidance is effective for annual reporting periods beginning after December 15, 2017 and interim periods therein. An entity can elect to apply the guidance under one of the following two methods: (i) retrospectively to each prior reporting period presented – referred to as the full retrospective method or (ii) retrospectively with the cumulative effect of initially applying the standard recognized at the date of initial application in retained earnings – referred to as the modified retrospective method.

We have substantially completed an initial impact assessment of the potential changes from adopting ASU 2014-09. The impact assessment consisted of a review of a representative sample of contracts, discussions with key stakeholders, and a cataloging of potential impacts on our financial statements, accounting policies, financial controls, and operations. We currently do not anticipate a material impact on our revenue recognition practices for product and royalty revenues. We do anticipate that the adoption of ASU 2014-09 will have primarily two impacts on our contract revenues generated by our collaborative research and license agreements:

(i)Changes in the model for distinct licenses of functional intellectual property which may result in a timing difference of revenue recognition. Whereas revenue from these arrangements was previously recognized over a period of time pursuant to revenue recognition guidance that was in place for our arrangements at the time such arrangements commenced, revenue from these arrangements may now be recognized at point in time under the new guidance.

(ii)Assessments of milestone payments, which are linked to events that are in our control, will result in variable consideration that may be recognized at an earlier point in time under the new guidance, when it is probable that the milestone will be achieved without a significant future reversal of cumulative revenue expected.

We have not yet completed our final review of the impact of this guidance including the new disclosure requirements, as we are continuing to evaluate the impacts of adoption and the implementation approach to be used. We plan to adopt the new standard effective January 1, 2018 and are considering adopting using the modified retrospective method. We continue to monitor additional changes, modifications, clarifications or interpretations being undertaken by the FASB, which may impact our current conclusions.

In February 2016, the FASB issued ASU No. 2016-02, “Leases,” that requires lessees to recognize assets and liabilities on the balance sheet for most leases including operating leases. Lessees now classify leases as either finance or operating leases and lessors classify all leases as sales-type, direct financing or operating leases. The statement of operations presentation and expense recognition for lessees for finance leases is similar to that of capital leases under Accounting Standards Codification (“ASC”) 840 with separate interest and amortization expense with higher periodic expense in the earlier periods of a lease. For operating leases, the statement of operations presentation and expense recognition is similar to that of operating leases under ASC 840 with single lease cost recognized on a straight-line basis. This guidance is to be applied using a modified retrospective approach at the beginning of the earliest comparative period presented in the financial statements and is effective for annual periods beginning after December 15, 2018 and interim periods therein. Early adoption is permitted. We are currently analyzing the impact of ASU No. 2016-02 and, at this time, are unable to determine the impact of the new standard on our condensed consolidated financial statements.

In October 2016, the FASB issued ASU No. 2016-16, “Intra-Entity Transfers of Assets Other Than Inventory,” which requires companies to account for the income tax effects of intercompany sales and transfers of assets other than inventory in the period in which the transfer occurs. The new standard is effective for public business entities for annual periods beginning after December 15, 2017 (i.e. 2018 for a calendar-year entity). The guidance will be applied for the annual period beginning January 1, 2018 using a modified retrospective approach with a cumulative catch-up

adjustment to opening retained earnings.

We have elected to early adopt ASU No. 2016-16 as of the first quarter of 2017, which requires us to reflect any adjustments as of January 1, 2017, the beginning of the annual period that includes the interim period of adoption. The primary impact of adoption was the recognition of a deferred tax asset of $34.9 million related to the excess of the tax

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basis over the consolidated book value basis in the intellectual property rights that were licensed from the U.S. parent company to our wholly-owned subsidiary in Switzerland during 2015 and a $2.1 million reversal of long-term prepaid taxes. Under previous guidance, companies were prohibited from recognizing an increase in tax basis and any income taxes incurred as a result of a sale or transfer of assets to companies that are part of a consolidated reporting entity. Given the full valuation allowance placed on the additional $34.9 million of deferred tax assets, the recognition upon adoption only required a $2.1 million adjustment to our retained earnings as of January 1, 2017 due to the adjustment of the prepaid tax asset.

In November 2016, the FASB issued ASU No. 2016-18, “Restricted Cash,” which requires entities to show the changes in total of cash, cash equivalents, restricted cash and restricted cash equivalents in the statement of cash flows. As a result, entities will no longer present transfers between cash and cash equivalents and restricted cash in the statement of cash flows. When cash, cash equivalents, restricted cash and restricted cash equivalents are presented in more than one line item on the balance sheet, the new guidance requires a reconciliation of the totals in the statement of cash flows to the related captions on the balance sheet. The reconciliation can either be presented either on the face of the statement of cash flows or in the notes to the financial statements. The new standard is effective for public business entities for fiscal years beginning after December 15, 2017 and interim periods therein and is to be applied retrospectively. Early adoption is permitted. We are currently analyzing the impact of ASU No. 2016-18 on our condensed consolidated financial statements.

In January 2017, the FASB issued ASU No. 2017-04, “Intangibles–Goodwill and Other,” which eliminates the requirement to calculate the implied fair value of goodwill to measure a goodwill impairment charge. Under the new standard, entities will record an impairment charge based on the excess of a reporting unit’s carrying amount over its fair value. The new standard is effective for public business entities that are SEC filers for annual or any interim goodwill impairment tests in fiscal years beginning after December 15, 2019. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. The standard is to be applied on a prospective basis. We are currently analyzing the impact of ASU No. 2017-04 on our condensed consolidated financial statements.

In March 2017, the FASB issued ASU No. 2017-07, “Compensation–Retirement Benefits,” which requires the presentation of the service cost component of the net periodic benefit cost in the same income statement line as other employee compensation costs arising from services rendered during the period. In addition, only the service cost component will be eligible for capitalization in assets. Disclosure of the line(s) used to present the other components of net periodic benefit cost, if the components are not presented separately in the income statement, is also required. The new standard is effective for public business entities for fiscal years beginning after December 15, 2017 and interim periods therein. The guidance on the presentation of the components of net periodic benefit cost in the income statement is to be applied retrospectively. The guidance limiting the capitalization of net periodic benefit cost in assets to the service cost component is to be applied prospectively. We are currently analyzing the impact of ASU No. 2017-07 on our condensed consolidated financial statements.

In July 2015, the FASB issued ASU No. 2015-11, “Simplifying the Measurement of Inventory,” which requires inventory to be measured at the lower of cost and net realizable value rather than at the lower of cost or market value. The new standard is effective for public business entities for fiscal years beginning after December 15, 2016 and interim periods therein. The guidance is to be applied prospectively. We adopted ASU No. 2015-11 as of the first quarter of 2017 and the adoption had no impact on our condensed consolidated financial statements.

Results of Operations

We recorded net income of $36.1 million and basic and diluted net income per share of $0.17 for the three months ended September 30, 2017, as compared to net income of $36.9 million and basic net income per share of $0.20 and

diluted net income per share of $0.19 in the corresponding period in 2016. We recorded net loss of $163.5 million and basic and diluted net loss per share of $0.81, for the nine months ended September 30, 2017, as compared to net income of $95.3 million and basic net income per share of $0.51 and diluted net income per share of $0.49 in the corresponding period in 2016.

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Revenues.

	For the Three Months Ended, September 30,		For the Nine Months Ended, September 30,	
	2017	2016	2017	2016
	(in millions)		(in millions)	
JAKAFI revenues, net	$ 303.9	$ 223.9	$ 831.0	$ 615.3
ICLUSIG revenues, net	18.1	12.7	47.5	16.7
Total product revenues, net	$ 322.0	$ 236.6	$ 878.5	$ 632.0
Product royalty revenues	44.5	29.6	108.5	77.5
Contract revenues	15.0	3.2	105.0	69.6
Other revenues	—	0.1	0.1	0.1
Total revenues	$ 381.5	$ 269.5	$ 1,092.1	$ 779.2

Our product revenues, net for the three and nine months ended September 30, 2017 were $322.0 million and $878.5 million, respectively. Our product revenues, net for the three and nine months ended September 30, 2016 were $236.6 million and $632.0 million, respectively. The increase in JAKAFI product revenues for the three months ended September 30, 2017 as compared to the corresponding period in 2016 was comprised of a volume increase of $57.0 million and a price increase of $23.0 million. The increase in JAKAFI product revenues for the nine months ended September 30, 2017 as compared to the corresponding period in 2016 was comprised of a volume increase of $155.1 million and a price increase of $60.6 million. ICLUSIG product revenues commenced in June 2016 following the Acquisition. Product revenues are recorded net of estimated product returns, pricing discounts including rebates offered pursuant to mandatory federal and state government programs and chargebacks, prompt pay discounts and distribution fees and co-pay assistance. Our revenue recognition policies require estimates of the aforementioned sales allowances each period.

The following table provides a summary of activity with respect to our sales allowances and accruals:

Nine Months Ended September 30, 2017	Discounts and Distribution Fees	Government Rebates and Chargebacks	Co-Pay Assistance and Other Discounts	Product Returns	Total
Balance at January 1, 2017	$ 2,818	$ 22,412	$ 199	$ 1,211	$ 26,640
Allowances for current period sales	23,936	106,331	3,401	668	134,336
Allowances for prior period sales	(59)	(971)	(10)	(353)	(1,393)
Credits/payments for current period sales	(21,759)	(82,363)	(3,225)	(34)	(107,381)
Credits/payments for prior period sales	(800)	(16,964)	(17)	(404)	(18,185)
Balance at September 30, 2017	$ 4,136	$ 28,445	$ 348	$ 1,088	$ 34,017

Government rebates and chargebacks are the most significant component of our sales allowances. Increases in certain government reimbursement rates are limited to a measure of inflation, and when the price of a drug increases faster than this measure of inflation it will result in a penalty adjustment factor that causes a larger sales allowance to those government related entities. We expect government rebates and chargebacks as a percentage of our gross product sales

will continue to increase in connection with any future JAKAFI price increases greater than the rate of inflation, and any such increase in these government rebates and chargebacks will have a negative impact on our reported product revenues, net. We adjust our estimates for government rebates and chargebacks based on new information regarding actual rebates as it becomes available. Claims by third-party payors for rebates and chargebacks are frequently submitted after the period in which the related sales occurred, which may result in adjustments to prior period accrual balances in the period in which the new information becomes available. We also adjust our allowance for product returns based on new information regarding actual returns as it becomes available.

We expect our sales allowances to fluctuate from quarter to quarter as a result of the Medicare Part D Coverage Gap, the volume of purchases eligible for government mandated discounts and rebates as well as changes in discount percentages which are impacted by potential future price increases, rate of inflation, and other factors.

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Product royalty revenues on commercial sales of JAKAVI by Novartis are based on net sales of licensed products in licensed territories as provided by Novartis. Our JAKAVI product royalty revenues for the three and nine months ended September 30, 2017 were $41.3 million and $104.0 million, respectively. Our JAKAVI product royalty revenues for the three and nine months ended September 30, 2016 were $29.6 million and $77.5 million, respectively. Product royalty revenues on commercial sales of OLUMIANT by Lilly are based on net sales of licensed products in licensed territories as provided by Lilly. Our OLUMIANT product royalty revenues for the three and nine months ended September 30, 2017 were $3.2 million and $4.5 million, respectively.

Our contract revenues were $15.0 million and $105.0 million for the three and nine months ended September 30, 2017, respectively. Our contract revenues were $3.2 million and $69.6 million for the three and nine months ended September 30, 2016, respectively. For the nine months ended September 30, 2017, contract revenues were derived from milestone payments from Lilly and Novartis earned during the period. For the nine months ended September 30, 2016, contract revenues were derived from the straight line recognition of revenue associated with the Lilly upfront fees over the estimated performance period as well as milestone payments from Lilly and Novartis earned during the period. During the nine months ended September 30, 2017, under the Lilly agreement, we recognized a $15.0 million regulatory milestone payment for the approval of baricitinib for the treatment of rheumatoid arthritis by Japan's Ministry of Health, Labor and Welfare and a $65.0 million regulatory milestone payment for the approval of baricitinib for the treatment of moderate-to-severe rheumatoid arthritis in adult patient by the European Commission and under the Novartis agreement, we recognized a $25.0 million development milestone payment based on the formal initiation by Novartis of a Phase III clinical trial evaluating ruxolitinib in the GVHD field. During the nine months ended September 30, 2016, under the Novartis agreement, we recognized a $5.0 million payment for the development and commercialization of ruxolitinib in GVHD outside of the United States and under the Lilly agreement, we recognized a $35.0 million regulatory milestone payment for the submission of a new drug application to the U.S. Food and Drug Administration for the approval of oral once-daily baricitinib for the treatment of moderate-to-severe rheumatoid arthritis and a $20.0 million regulatory milestone for the submission of a Marketing Authorization Application to the European Medicines Agency for the approval of oral once-daily baricitinib for the treatment of moderate-to-severe rheumatoid arthritis.

Cost of Product Revenues.

	For the Three Months Ended, September 30,		For the Nine Months Ended, September 30,	
	2017	2016	2017	2016
	(in millions)		(in millions)	
Product costs	$ 1.7	$ 3.8	$ 5.2	$ 6.3
Royalty expense	14.9	11.0	35.7	25.1
Amortization of definite-lived intangible assets	5.4	5.4	16.2	7.2
Total cost of product revenues	$ 22.0	$ 20.2	$ 57.1	$ 38.6

Cost of product revenues includes all JAKAFI related product costs, all ICLUSIG related product costs and low single digit royalties to Novartis on all sales of JAKAFI in the United States. The ICLUSIG inventories were recorded at fair value less costs to sell in connection with the Acquisition, which resulted in a higher cost of ICLUSIG product revenues over a one year period from the acquisition date. Subsequent to the acquisition on June 1, 2016, cost of product revenues also includes the amortization of our licensed intellectual property for ICLUSIG using the straight-line method over the estimated useful life of 12.5 years.

Cost of product revenues was $22.0 million and $57.1 million for the three and nine months ended September 30, 2017, respectively. Cost of product revenues was $20.2 million and $38.6 million for the three and nine months ended

September 30, 2016, respectively. The increase in cost of product revenues for the three and nine months ended September 30, 2017 as compared to the same periods in 2016 is due primarily to increased royalties to Novartis on all JAKAFI sales in the United States and amortization of our licensed intellectual property acquired on June 1, 2016.

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Operating Expenses.

Research and development expenses.

	For the Three Months Ended, September 30,		For the Nine Months Ended, September 30,	
	2017	2016	2017	2016
	(in millions)		(in millions)	
Salary and benefits related	$ 51.4	$ 36.7	$ 141.6	$ 101.5
Stock compensation	23.4	16.2	67.8	42.8
Clinical research and outside services	173.9	76.1	612.6	235.7
Occupancy and all other costs	20.9	14.2	57.4	40.3
Total research and development expenses	$ 269.6	$ 143.2	$ 879.4	$ 420.3

We currently account for research and development costs by natural expense line and not costs by project. Salary and benefits related expense increased from the three and nine months ended September 30, 2016 to the three and nine months ended September 30, 2017 due primarily to increased development headcount to sustain our development pipeline. Stock compensation expense may fluctuate from period to period based on the number of awards granted, stock price volatility and expected award lives, as well as expected award forfeiture rates which are used to value equity-based compensation.

The increase in clinical research and outside services expense from the three and nine months ended September 30, 2016 to the three and nine months ended September 30, 2017 was primarily due to upfront and milestone expenses related to our collaborative agreements, as well as an overall increase in development costs to advance our clinical pipeline. Specifically, we recorded charges for the new Calithera and Merus agreements, and the amended Agenus agreement, during the nine months ended September 30, 2017. The total charges recorded for these agreements was $209.1 million during the nine months ended September 30, 2017. In addition, research and development expenses for the nine months ended September 30, 2017 includes expense related to Incyte Biosciences Luxembourg S.à.r.l. resulting from the Acquisition on June 1, 2016. Research and development expenses for the nine months ended September 30, 2017 and 2016 were net of $3.2 million, $12.3 million, $3.7 million and $11.0 million, respectively, of costs reimbursed by our collaborative partners. Research and development expenses may fluctuate from period to period depending upon the stage of certain projects and the level of pre clinical and clinical trial related activities. Many factors can affect the cost and timing of our clinical trials, including requests by regulatory agencies for more information, inconclusive results requiring additional clinical trials, slow patient enrollment, adverse side effects among patients, insufficient supplies for our clinical trials and real or perceived lack of effectiveness or safety of our investigational drugs in our clinical trials. In addition, the development of all of our products will be subject to extensive governmental regulation. These factors make it difficult for us to predict the timing and costs of the further development and approval of our products.

In July 2010, we elected to co-develop baricitinib with Lilly in rheumatoid arthritis and we are responsible for funding 30% of the associated future global development costs for this indication from the initiation of the Phase IIb trial through regulatory approval. In January 2017, we exercised our co-development option in psoriatic arthritis to fund 30% of future global development costs through regulatory approval, including post-launch studies required by a regulatory authority. We also exercised our co-development options in both atopic dermatitis and axial spondyloarthritis, should Lilly decide to progress into a pivotal program in these indications. Research and development expenses recorded under the Lilly agreement representing 30% of the global development costs for baricitinib for the treatment of rheumatoid arthritis, psoriatic arthritis and atopic dermatitis were $9.1 million and $27.2 million for the three and nine months ended September 30, 2017, respectively. Research and development

expenses recorded under the Lilly agreement representing 30% of the global development costs for baricitinib for the treatment of rheumatoid arthritis were $10.6 million and $21.0 million for the three and nine months ended September 30, 2016, respectively. We have retained certain mechanisms to give us cost protection as baricitinib advances in clinical development. We can defer our portion of co-development study costs by indication if they exceed a predetermined level. This deferment would be credited against future milestones or royalties and we would still be eligible for the full incremental royalties related to the co-development option. In addition, even if we have started co-development funding for any indication, we can at any time opt out, which will stop future co-development cost sharing. If we elect to do this we would still be eligible for our base royalties plus an incremental pro-

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rated royalty commensurate with our contribution to the total co-development cost for those indications for which we contributed funding.

Selling, general and administrative expenses.

	For the Three Months Ended, September 30,		For the Nine Months Ended, September 30,	
	2017	2016	2017	2016
	(in millions)		(in millions)	
Salary and benefits related	$ 27.4	$ 23.2	$ 76.9	$ 58.7
Stock compensation	11.5	10.3	31.5	25.8
Other contract services and outside costs	52.4	42.3	160.2	122.7
Total selling, general and administrative expenses	$ 91.3	$ 75.8	$ 268.6	$ 207.2

Salary and benefits related expense increased from the three and nine months ended September 30, 2016 to the three and nine months ended September 30, 2017 due to increased headcount. This increased headcount was due primarily to the ongoing commercialization efforts related to JAKAFI for intermediate or high risk myelofibrosis and uncontrolled polycythemia vera, as well as increased headcount related to the Acquisition on June 1, 2016. Stock compensation expense may fluctuate from period to period based on the number of awards granted, stock price volatility and expected award lives, as well as expected award forfeiture rates which are used to value equity based compensation. The increase in other contract services and outside costs was primarily the result of marketing activities for JAKAFI for intermediate or high risk myelofibrosis and uncontrolled polycythemia vera in addition to an increase in donations to independent non-profit patient assistance organizations in the United States.

Change in fair value of acquisition-related contingent consideration

Acquisition-related contingent consideration, which consists of our future royalty and certain potential milestone obligations to ARIAD, was recorded on the acquisition date, June 1, 2016, at the estimated fair value of the obligation, in accordance with the acquisition method of accounting. The fair value of the acquisition-related contingent consideration is remeasured quarterly, resulting in a benefit of $16.3 million and $1.9 million for the three and nine months ended September 30, 2017, respectively, which is recorded in change in fair value of acquisition-related contingent consideration on the condensed consolidated statements of operations. The change in fair value of the acquisition-related contingent consideration for the three and nine months ended September 30, 2016 was expense of $8.0 million and $10.3 million, respectively, which is recorded in change in fair value of acquisition-related contingent consideration on the condensed consolidated statements of operations. The change in fair value of the contingent consideration for the three and nine months ended September 30, 2017 is due to the passage of time and a benefit of $24.0 million recorded during the third quarter related to the lack of expected future sales royalties payable due to the discontinued OPTIC-2L clinical trial.

Other income (expense).

Interest and other income, net. Interest and other income, net, for the three and nine months ended September 30, 2017 was $5.6 million and $10.9 million, respectively. Interest and other income, net, for the three and nine months ended September 30, 2016 was and $1.2 million and $3.8 million, respectively.

Interest expense. Interest expense for the three and nine months ended September 30, 2017 was $0.2 million and $6.5 million, respectively, as compared to $9.5 million and $29.3 million, respectively, for the same periods in 2016. The decrease in interest expense during the three and nine months ended September 30, 2017 relates to the conversion of

senior notes during the period. Included in interest expense for the three and nine months ended September 30, 2017 was $0.3 million and $5.8 million, respectively, of non-cash charges to amortize the discounts on the 2018 Notes and the 2020 Notes. Included in interest expense for the three and nine months ended September 30, 2016 was $7.9 million and $23.6 million, respectively, of non-cash charges to amortize the discounts on the 2018 Notes and the 2020 Notes.

Unrealized gain (loss) on long term investments. Unrealized gains (losses) on long term investments will fluctuate from period to period, based on the change in fair value of the securities we hold in our publicly held collaboration partners.

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With respect to our long term investment in Agenus, the unrealized gain on investment for the three and nine months ended September 31, 2017 was $10.2 million and $6.8 million, respectively, as compared to the unrealized gain of $24.3 million and $20.5 million, respectively, for the same periods in 2016. The unrealized gain on our long term investment in Merus for the three months ended September 30, 2017 was $12.9 million and the unrealized loss for the nine months ended September 30, 2017 was $9.2 million.

Expense related to senior note conversions. Expense related to senior note conversions for the three and nine months ended September 30, 2017 was $0.0 million and $54.9 million, respectively, on the conversions of our 2018 Notes and 2020 Notes.

Liquidity and Capital Resources

Due to historical net losses, we had an accumulated deficit of $1.8 billion as of September 30, 2017. We have funded our research and development operations through sales of equity securities, the issuance of convertible notes, cash received from customers, and collaborative arrangements. At September 30, 2017, we had available cash, cash equivalents and marketable securities of $1.3 billion. Our cash and marketable securities balances are held in a variety of interest-bearing instruments, including money market accounts, corporate debt securities and U.S. government securities. Available cash is invested in accordance with our investment policy’s primary objectives of liquidity, safety of principal and diversity of investments.

Net cash used by operating activities was $3.7 million for the nine months ended September 30, 2017, compared to $210.4 million provided by operating activities for the nine months ended September 30, 2016. The $214.1 million decrease in cash provided by operating activities was due primarily to the payments made to our collaborative partners for new or amended arrangements during the first quarter of 2017, expense related to our senior note conversions and changes in working capital during the 2017 period.

Our investing activities, other than purchases, sales and maturities of marketable securities, have consisted predominantly of capital expenditures and purchases of long term investments. Net cash used by investing activities was $207.0 million for the nine months ended September 30, 2017, which represented purchases of marketable securities of $131.9 million, capital expenditures of $85.8 million and purchases of long term investments of $123.9 million, offset in part by the sale and maturity of marketable securities of $134.6 million. Net cash used in investing activities was $196.5 million for the nine months ended September 30, 2016, which represented purchases of marketable securities of $26.9 million, capital expenditures of $104.4 million and acquisition of ARIAD Pharmaceuticals (Luxembourg) S.a.r.l. for net cash of $143.0 million, offset in part by the sale and maturity of marketable securities of $77.8 million. In the future, net cash used by investing activities may fluctuate significantly from period to period due to the timing of strategic equity investments, acquisitions and capital expenditures and maturities/sales and purchases of marketable securities.

Net cash provided by financing activities was $686.4 million and $44.8 million for the nine months ended September 30, 2017 and 2016, respectively, primarily representing proceeds from the issuance of common stock in our September 2017 public offering and, to a lesser extent, proceeds from the issuance of common stock under our stock plans and employee stock purchase plan, offset in part by cash paid to ARIAD for contingent consideration and cash paid in connection with senior note conversions.

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The following summarizes our significant contractual obligations as of September 30, 2017 and the effect those obligations are expected to have on our liquidity and cash flow in future periods (in millions):

	Total	Less Than 1 Year	Years 2 - 3	Years 4 - 5	Over 5 Years
Contractual Obligations:					
Principal on convertible senior debt	$ 26.8	$ —	$ 7.7	$ 19.1	$ —
Interest on convertible senior debt	0.9	0.3	0.5	0.1	—
Non-cancelable lease obligations	28.8	12.4	12.5	2.3	1.6
Total contractual obligations	$ 56.5	$ 12.7	$ 20.7	$ 21.5	$ 1.6

We have entered into and may in the future seek to license additional rights relating to technologies or drug development candidates in connection with our drug discovery and development programs. Under these licenses, we may be required to pay upfront fees, milestone payments, and royalties on sales of future products, which are not reflected in the table above.

We believe that our cash flow from operations, together with our cash, cash equivalents and marketable securities, will be adequate to satisfy our capital needs for at least the next twelve months. Our cash requirements depend on numerous factors, including our expenditures in connection with our drug discovery and development programs and commercialization operations; expenditures in connection with litigation or other legal proceedings; competing technological and market developments; the cost of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights; costs for future facility requirements; our receipt of any milestone or other payments under any collaborative agreements we may enter into, including the agreements with Novartis and Lilly; expenditures in connection with potential exchanges of our outstanding convertible senior notes; and expenditures in connection with strategic relationships and license agreements, including our agreements with Agenus, ARIAD, Calithera, Hengrui, Lilly, MacroGenics and Merus, strategic equity investments or potential acquisitions. Changes in our research and development or commercialization plans or other changes affecting our operating expenses may result in changes in the timing and amount of expenditures of our capital resources. To the extent we seek to augment our existing cash resources and cash flow from operations to satisfy our cash requirements, we expect that additional funding can be obtained primarily through public or private equity offerings, debt financings, borrowings or strategic collaborations. The sale of equity or additional convertible debt securities in the future may be dilutive to our stockholders, and may provide for rights, preferences or privileges senior to those of our holders of common stock. Debt financing arrangements may require us to pledge certain assets or enter into covenants that could restrict our operations or our ability to incur further indebtedness.

Off Balance Sheet Arrangements

We have no off-balance sheet arrangements other than those that are discussed above.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our investments in marketable securities, which are composed primarily of corporate debt securities and U.S. government securities, are subject to default, changes in credit rating and changes in market value. These investments are also subject to interest rate risk and will decrease in value if market rate interest rates increase. As of September 30, 2017, marketable securities were $153.3 million. Due to the nature of these investments, if market interest rates were to increase immediately and uniformly by 10% from levels as of September 30, 2017, the decline in fair value would not be material.

Item 4. Controls and Procedures

Evaluation of disclosure controls and procedures. We maintain "disclosure controls and procedures," as such term is defined in Rule 13a-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act"), that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing

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and evaluating our disclosure controls and procedures, management recognized that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Our disclosure controls and procedures have been designed to meet reasonable assurance standards. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Based on their evaluation as of the end of the period covered by this Quarterly Report on Form 10-Q, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in internal control over financial reporting. There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) for the nine months ended September 30, 2017, that materially affected or are reasonably likely to materially affect our internal control over financial reporting.

PART II: OTHER INFORMATION

Item 1A. Risk Factors

RISKS RELATING TO COMMERCIALIZATION OF OUR PRODUCTS

We depend heavily on our lead product, JAKAFI (ruxolitinib), which is marketed as JAKAVI outside the United States. If we are unable to successfully commercialize JAKAFI in its approved indications or to successfully obtain regulatory approval for and commercialize ruxolitinib for the treatment of additional indications, or if we are significantly delayed or limited in doing so, our business may be materially harmed.

JAKAFI is our first and, currently, only product approved for sale in the United States. It was approved by the U.S. Food and Drug Administration, or FDA, in November 2011 for the treatment of patients with intermediate or high risk myelofibrosis and in December 2014 for the treatment of patients with polycythemia vera who have had an inadequate response to or are intolerant of hydroxyurea, which we refer to as uncontrolled polycythemia vera. Although we have received regulatory approval for these indications, such approval does not guarantee future revenues. While we recently acquired exclusive rights to develop and commercialize ICLUSIG in the European Union, or EU, and other countries, we anticipate that JAKAFI product sales will continue to contribute a significant percentage of our total revenues over the next several years.

The commercial success of JAKAFI and our ability to generate and maintain revenues from the sale of JAKAFI will depend on a number of factors, including:

- the number of patients with intermediate or high risk myelofibrosis or uncontrolled polycythemia vera who are diagnosed with the disease and the number of such patients that may be treated with JAKAFI;
- the acceptance of JAKAFI by patients and the healthcare community;
- whether physicians, patients and healthcare payors view JAKAFI as therapeutically effective and safe relative to cost and any alternative therapies;
- the ability to obtain and maintain sufficient coverage or reimbursement by third party payors;
- the ability of our third party manufacturers to manufacture JAKAFI in sufficient quantities with acceptable quality;

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- the ability of our company and our third party providers to provide marketing and distribution support for JAKAFI;
- the label and promotional claims allowed by the FDA;
- the maintenance of regulatory approval for the approved indications in the United States; and
- our ability to develop, obtain regulatory approval for and commercialize ruxolitinib in the United States for additional indications.

If we are not successful in commercializing JAKAFI in the United States, or are significantly delayed or limited in doing so, our business may be materially harmed and we may need to delay other drug discovery and development initiatives or even significantly curtail operations.

In addition, our receipt of royalties under our collaboration agreement with Novartis for sales of JAKAVI outside the United States will depend on factors similar to those listed above for jurisdictions outside the United States.

If we are unable to obtain, or maintain at anticipated levels, reimbursement for our products from government health administration authorities, private health insurers and other organizations, our pricing may be affected or our product sales, results of operations or financial condition could be harmed.

We may not be able to sell our products on a profitable basis or our profitability may be reduced if we are required to sell our products at lower than anticipated prices or reimbursement is unavailable or limited in scope or amount. JAKAFI and ICLUSIG are expensive and almost all patients will require some form of third party coverage to afford their cost. Our future revenues and profitability will be adversely affected if we cannot depend on government and other third party payors to defray the cost of our products to the patient. Reimbursement systems in international markets vary significantly by country and by region, and reimbursement approvals must be obtained on a country-by-country basis. Reimbursement in the EU must be negotiated on a country-by-country basis and in many countries the product cannot be commercially launched until reimbursement is approved. The timing to complete the negotiation process in each country is highly uncertain, and in some countries, we expect that it may exceed 12 months. Risks related to pricing and reimbursement are described below under "—Other Risks Relating to our Business—Health care reform measures could impact the pricing and profitability of pharmaceuticals, and adversely affect the commercial viability of our products and drug candidates. Our ability to generate revenues will be diminished if we are unable to obtain an adequate level of reimbursement from private insurers, government insurance programs or other third party payors of health care costs, which could be affected by current and potential healthcare reform legislation." If government and other third party payors refuse to provide coverage and reimbursement with respect to our products, determine to provide a lower level of coverage and reimbursement than anticipated, or reduce previously approved levels of coverage and reimbursement, then our pricing or reimbursement for our products may be affected and our product sales, results of operations or financial condition could be harmed.

We depend upon a limited number of specialty pharmacies and wholesalers for a significant portion of any revenues from JAKAFI, and the loss of, or significant reduction in sales to, any one of these specialty pharmacies or wholesalers could adversely affect our operations and financial condition.

We sell JAKAFI primarily to specialty pharmacies and wholesalers. Specialty pharmacies dispense JAKAFI to patients in fulfillment of prescriptions and wholesalers sell JAKAFI to hospitals and physician offices. We do not promote JAKAFI to specialty pharmacies or wholesalers, and they do not set or determine demand for JAKAFI. Our ability to successfully commercialize JAKAFI will depend, in part, on the extent to which we are able to provide adequate distribution of JAKAFI to patients. Although we have contracted with a number of specialty pharmacies and wholesalers, they are expected generally to carry a very limited inventory and may be reluctant to be part of our distribution network in the future if demand for the product does not increase. Further, it is possible that these specialty pharmacies and wholesalers could decide to change their policies or fees, or both, at some time in the future. This could result in their refusal to carry smaller volume products such as JAKAFI, or lower margins or the need to find alternative methods of distributing our product. Although we believe we can find alternative channels to

distribute JAKAFI on relatively short notice, our revenue

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during that period of time may suffer and we may incur additional costs to replace any such specialty pharmacy or wholesaler. The loss of any large specialty pharmacy or wholesaler as part of our distribution network, a significant reduction in sales we make to specialty pharmacies or wholesalers, or any failure to pay for the products we have shipped to them could materially and adversely affect our results of operations and financial condition.

If we are unable to establish and maintain effective sales, marketing and distribution capabilities, or to enter into agreements with third parties to do so, we will not be able to successfully commercialize our products.

Prior to our commercialization of JAKAFI, we had no experience selling and marketing drug products and with pricing and obtaining adequate third party reimbursement for drug products. Under our collaboration and license agreement with Novartis, we have retained commercialization rights to JAKAFI in the United States. We have established commercial capabilities in the United States, but cannot guarantee that we will be able to enter into and maintain any marketing, distribution or third party logistics agreements with third party providers on acceptable terms, if at all. In connection with our recent acquisition from ARIAD Pharmaceuticals, Inc. we licensed rights to develop and commercialize ICLUSIG in certain countries and we acquired the European sales, marketing and distribution operations of ARIAD. We may not be able to maintain those operations or retain their personnel or distribution arrangements. We may not be able to correctly judge the size and experience of the sales and marketing force and the scale of distribution capabilities necessary to successfully market and sell our products. Establishing and maintaining sales, marketing and distribution capabilities are expensive and time consuming. Competition for personnel with experience in sales and marketing can be high. Our expenses associated with building and maintaining the sales force and distribution capabilities may be disproportional compared to the revenues we may be able to generate on sales of our products.

If we fail to comply with applicable laws and regulations, we could lose our approval to market our products or be subject to other governmental enforcement activity.

We cannot guarantee that we will be able to maintain regulatory approval to market our products in the jurisdictions in which they are currently marketed. If we do not maintain our regulatory approval to market our products, in particular JAKAFI, our results of operations will be materially harmed. We and our collaborators, third party manufacturers and suppliers are subject to rigorous and extensive regulation by the FDA and other federal and state agencies as well as foreign governmental agencies. These regulations continue to apply after product marketing approval, and cover, among other things, testing, manufacturing, quality control, labeling, advertising, promotion, risk mitigation, and adverse event reporting requirements.

The commercialization of our products is subject to post regulatory approval product surveillance, and our products may have to be withdrawn from the market or subject to restrictions if previously unknown problems occur. Regulatory agencies may also require additional clinical trials or testing for our products, and our products may be recalled or may be subject to reformulation, additional studies, changes in labeling, warnings to the public and negative publicity. For example, from late 2013 through 2014, ICLUSIG was subject to review by the European Medicines Agency, or EMA, of the benefits and risks of ICLUSIG to better understand the nature, frequency and severity of events obstructing the arteries or veins, the potential mechanism that leads to these side effects and whether there needed to be a revision in the dosing recommendation, patient monitoring and a risk management plan for ICLUSIG. This review was completed in January 2015, with additional warnings in the product information but without any change in the approved indications. The EMA could take additional actions in the future that reduce the commercial potential of ICLUSIG.

Failure to comply with the laws and regulations administered by the FDA or other agencies could result in:

· administrative and judicial sanctions, including warning letters;

- fines and other civil penalties;
- suspension or withdrawal of regulatory approval to market our products;
- interruption of production;

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- operating restrictions;
- product recall or seizure;
- injunctions; and
- criminal prosecution.

The occurrence of any such event may have a material adverse effect on our business.

If the use of our products harms patients, or is perceived to harm patients even when such harm is unrelated to our products, our regulatory approvals could be revoked or otherwise negatively impacted or we could be subject to costly and damaging product liability claims.

The testing of JAKAFI and ICLUSIG, the manufacturing, marketing and sale of JAKAFI and the marketing and sale of ICLUSIG expose us to product liability and other risks. Side effects and other problems experienced by patients from the use of our products could:

- lessen the frequency with which physicians decide to prescribe our products;
- encourage physicians to stop prescribing our products to their patients who previously had been prescribed our products;
- cause serious harm to patients that may give rise to product liability claims against us; and
- result in our need to withdraw or recall our products from the marketplace.

If our products are used by a wide patient population, new risks and side effects may be discovered, the rate of known risks or side effects may increase, and risks previously viewed as less significant could be determined to be significant.

Previously unknown risks and adverse effects of our products may also be discovered in connection with unapproved, or off label, uses of our products. We are prohibited by law from promoting or in any way supporting or encouraging the promotion of our products for off label uses, but physicians are permitted to use products for off label purposes. In addition, we are studying and expect to continue to study JAKAFI in diseases for potential additional indications in controlled clinical settings, and independent investigators are doing so as well. In the event of any new risks or adverse effects discovered as new patients are treated for intermediate or high risk myelofibrosis or uncontrolled polycythemia vera and as JAKAFI is studied in or used by patients for off label indications, regulatory authorities may delay or revoke their approvals, we may be required to conduct additional clinical trials, make changes in labeling of JAKAFI, reformulate JAKAFI or make changes and obtain new approvals. We may also experience a significant drop in the sales of JAKAFI, experience harm to our reputation and the reputation of JAKAFI in the marketplace or become subject to lawsuits, including class actions. Any of these results could decrease or prevent sales of JAKAFI or substantially increase the costs and expenses of commercializing JAKAFI. Similar results could occur with respect to our commercialization of ICLUSIG.

Patients who have been enrolled in our clinical trials or who may use our products in the future often have severe and advanced stages of disease and known as well as unknown significant pre existing and potentially life threatening health risks. During the course of treatment, patients may suffer adverse events, including death, for reasons that may or may not be related to our products. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively impact or end our opportunity to receive or maintain regulatory approval to market our products, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which we do not believe that an adverse event is related to our products, the investigation into the circumstance may be time

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consuming or inconclusive. These investigations may interrupt our sales efforts, impact and limit the type of regulatory approvals our products receive or maintain, or delay the regulatory approval process in other countries.

Factors similar to those listed above also apply to our collaboration partner Novartis and to ICLUSIG for jurisdictions outside the United States.

If we market our products in a manner that violates various laws and regulations, we may be subject to civil or criminal penalties.

In addition to FDA and related regulatory requirements, we are subject to health care "fraud and abuse" laws, such as the federal False Claims Act, the anti kickback provisions of the federal Social Security Act, and other state and federal laws and regulations. Federal and state anti kickback laws prohibit, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any health care item or service reimbursable under Medicare, Medicaid, or other federally or state financed health care programs. Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Pharmaceutical companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities.

Although physicians are permitted, based on their medical judgment, to prescribe products for indications other than those approved by the FDA, manufacturers are prohibited from promoting their products for such off label uses. We market JAKAFI for intermediate or high risk myelofibrosis and uncontrolled polycythemia vera and provide promotional materials to physicians regarding the use of JAKAFI for these indications. Although we believe that our promotional materials for physicians do not constitute off label promotion of JAKAFI, the FDA or other agencies may disagree. If the FDA or another agency determines that our promotional materials or other activities constitute off label promotion of JAKAFI, it could request that we modify our promotional materials or other activities or subject us to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they believe that the alleged improper promotion led to the submission and payment of claims for an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. Even if it is later determined we are not in violation of these laws, we may be faced with negative publicity, incur significant expenses defending our position and have to divert significant management resources from other matters.

The European Union and member countries impose similar strict restrictions on the promotion and marketing of drug products. The off-label promotion of medicinal products is prohibited in the EU and in other territories. The promotion of medicinal products that are not subject to a marketing authorization is also prohibited in the EU. Violations of the rules governing the promotion of medicinal products in the EU and in other territories could be penalized by administrative measures, fines and imprisonment.

The majority of states also have statutes or regulations similar to the federal anti kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. In recent years, several states and localities, including California, Connecticut, the District of Columbia, Massachusetts, Minnesota, Nevada, New Mexico, Texas, Vermont, and West Virginia, have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Similar legislation is being considered in other states. Additionally, as part of the Patient Protection and Affordable Care Act, the federal government has enacted the Physician Payment Sunshine provisions. The Sunshine provisions require manufacturers to publicly report certain payments or other transfers of value made to physicians and teaching

hospitals. Many of these requirements are new and uncertain, and the penalties for failure to comply with these requirements are unclear. Nonetheless, if we are found not to be in full compliance with these laws, we could face enforcement action and fines and other penalties, and could receive adverse publicity. See also "—Other Risks Relating to our Business—If we fail to comply with the extensive legal and regulatory requirements affecting the health care industry, we could face increased costs, penalties and a loss of business" below.

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Competition for our products could harm our business and result in a decrease in our revenue.

Present and potential competitors for JAKAFI could include major pharmaceutical and biotechnology companies, as well as specialty pharmaceutical firms. For example, Gilead Sciences, Inc. has a drug candidate in Phase III clinical trials for the treatment of myelofibrosis. See "—Other Risks Relating to our Business— We face significant competition for our drug discovery and development efforts, and if we do not compete effectively, our commercial opportunities will be reduced or eliminated" for a description of risks relating to this type of competition. In addition, JAKAFI could face competition from generic products. As a result of the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, in the United States, generic manufacturers may seek approval of a generic version of an innovative pharmaceutical by filing with the FDA an Abbreviated New Drug Application, or ANDA. The Hatch-Waxman Act provides significant incentives to generic manufacturers to challenge U.S. patents on successful innovative pharmaceutical products. In February 2016, we received a notice letter regarding an ANDA that requested approval to market a generic version of JAKAFI and purported to challenge patents covering ruxolitinib phosphate and its use that expire in 2028. There can be no assurance that our patents will be upheld or that any litigation in which we might engage with any such generic manufacturer would be successful in protecting JAKAFI's exclusivity. The entry of a generic version of JAKAFI could result in a decrease in JAKAFI sales and materially harm our business, operating results and financial condition.

ICLUSIG currently competes with existing therapies that are approved for the treatment of patients with chronic myeloid leukemia, or CML, who are resistant or intolerant to prior tyrosine kinase inhibitor, or TKI, therapies, on the basis of, among other things, efficacy, cost, breadth of approved use and the safety and side-effect profile. In addition, a generic version of imatinib was launched in the United States in February 2016, and generic versions are expected to be launched in other markets. Although we currently believe that generic versions of imatinib will not materially impact our commercialization of ICLUSIG, given ICLUSIG's various indication statements globally that are currently focused on resistant or intolerant CML, we cannot be certain how physicians, payors, patients, regulatory authorities and other market participants will respond to the availability of generic versions of imatinib.

OTHER RISKS RELATING TO OUR BUSINESS

We may be unsuccessful in our efforts to discover and develop drug candidates and commercialize drug products.

None of our drug candidates, other than JAKAFI/JAKAVI, has received regulatory approval. Our ability to discover and develop drug candidates and to commercialize additional drug products will depend on our ability to:

- hire and retain key employees;
- identify high quality therapeutic targets;
- identify potential drug candidates;
- develop products internally or license drug candidates from others;
  - identify and enroll suitable human subjects, either in the United States or abroad, for our clinical trials;
- complete laboratory testing;
- commence, conduct and complete safe and effective clinical trials on humans;
- obtain and maintain necessary intellectual property rights to our products;
- obtain and maintain necessary regulatory approvals for our products, both in the United States and abroad;
- enter into arrangements with third parties to provide services or to manufacture our products on our behalf;

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- deploy sales and marketing resources effectively or enter into arrangements with third parties to provide these functions in compliance with all applicable laws;
- obtain appropriate coverage and reimbursement levels for the cost of our products from governmental authorities, private health insurers and other third party payors;
- lease facilities at reasonable rates to support our growth; and
- enter into arrangements with third parties to license and commercialize our products.

We have limited experience with many of the activities listed above and may not be successful in discovering, developing, or commercializing additional drug products. Discovery and development of drug candidates are expensive, uncertain and time consuming, and we do not know if our efforts will lead to discovery of any drug candidates that can be successfully developed and marketed. Of the compounds or biologics that we identify as potential drug products or that we may in license from other companies, including potential products for which we are conducting clinical trials, only a few, if any, are likely to lead to successful drug development programs and commercialized drug products.

We depend heavily on the success of our most advanced drug candidates. We might not be able to commercialize any of our drug candidates successfully, and we may spend significant time and money attempting to do so.

We have invested significant resources in the development of our most advanced drug candidates. Ruxolitinib recently entered into a pivotal Phase II clinical trial for the treatment of patients with steroid-refractory acute graft-versus-host disease and is in other clinical trials. Epacadostat commenced Phase III clinical trials in late 2016. Further, we have a number of drug candidates in Phase I and Phase II clinical trials. Our ability to generate product revenues will depend on the successful development and eventual commercialization of our most advanced drug candidates. We, or our collaborators or licensees, may decide to discontinue development of any or all of our drug candidates at any time for commercial, scientific or other reasons. For example, in early 2016, we decided to discontinue the studies of ruxolitinib in pancreatic cancer and solid tumors and INCB39110 in pancreatic cancer. If a product is developed but not approved or marketed, we may have spent significant amounts of time and money on it, which could adversely affect our operating results and financial condition as well as our business plans.

If we or our collaborators are unable to obtain regulatory approval for our drug candidates in the United States and foreign jurisdictions, we or our collaborators will not be permitted to commercialize products resulting from our research.

In order to commercialize drug products in the United States, drug candidates will have to obtain regulatory approval from the FDA. Satisfaction of regulatory requirements typically takes many years. To obtain regulatory approval, we or our collaborators, as the case may be, must first show that our drug candidates are safe and effective for target indications through preclinical testing (animal testing) and clinical trials (human testing). Preclinical testing and clinical development are long, expensive and uncertain processes, and we do not know whether the FDA will allow us or our collaborators to undertake clinical trials of any drug candidates in addition to our compounds currently in clinical trials. If regulatory approval of a product is granted, this approval will be limited to those disease states and conditions for which the product is demonstrated through clinical trials to be safe and effective.

Completion of clinical trials may take several years and failure may occur at any stage of testing. The length of time required varies substantially according to the type, complexity, novelty and intended use of the drug candidate. Interim results of a preclinical test or clinical trial do not necessarily predict final results, and acceptable results in early clinical trials may not be repeated in later clinical trials. For example, a drug candidate that is successful at the preclinical level may cause harmful or dangerous side effects when tested at the clinical level. Our rate of commencement and completion of clinical trials may be delayed, and existing clinical trials with our drug candidates may be stopped, due to many potential factors, including:

· the high degree of risk and uncertainty associated with drug development;

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- our inability to formulate or manufacture sufficient quantities of materials for use in clinical trials;
- variability in the number and types of patients available for each study;
- difficulty in maintaining contact with patients after treatment, resulting in incomplete data;
- unforeseen safety issues or side effects;
- poor or unanticipated effectiveness of drug candidates during the clinical trials; or
- government or regulatory delays.

Data obtained from clinical trials are susceptible to varying interpretation, which may delay, limit or prevent regulatory approval. Many companies in the pharmaceutical and biopharmaceutical industry, including our company, have suffered significant setbacks in advanced clinical trials, even after achieving promising results in earlier clinical trials. In addition, regulatory authorities may refuse or delay approval as a result of other factors, such as changes in regulatory policy during the period of product development and regulatory agency review. For example, the FDA has in the past required and could in the future require that we or our collaborators conduct additional trials of any of our drug candidates, which would result in delays. In April 2017, we and our collaborator Lilly announced that the FDA had issued a complete response letter for the New Drug Application (NDA) of OLUMIANT (baricitinib) as a once-daily oral medication for the treatment of moderate-to-severe rheumatoid arthritis. The letter indicates that the FDA is unable to approve the application in its current form. Specifically, the FDA indicated that additional clinical data are needed to determine the most appropriate doses. The FDA also stated that additional data are necessary to further characterize safety concerns across treatment arms. In July 2017, we and Lilly announced that a resubmission to the FDA for the NDA for baricitinib will be delayed for a period anticipated to be a minimum of 18 months and that the FDA had requested an additional clinical study.

Compounds or biologics developed by us or with or by our collaborators and licensees may not prove to be safe and effective in clinical trials and may not meet all of the applicable regulatory requirements needed to receive marketing approval. For example, in January 2016, a Phase II trial that was evaluating ruxolitinib in combination with regorafenib in patients with relapsed or refractory metastatic colorectal cancer and high C-reactive protein was stopped early after a planned analysis of interim efficacy data determined that the likelihood of the trial meeting its efficacy endpoint was insufficient. In addition, in February 2016, we made a decision to discontinue our JANUS 1 study, our JANUS 2 study, our other studies of ruxolitinib in colorectal, breast and lung cancer, and our study of INCB39110 in pancreatic cancer after a planned analysis of interim efficacy data of JANUS 1 demonstrated that ruxolitinib plus capecitabine did not show a sufficient level of efficacy to warrant continuation. If clinical trials of any of our compounds or biologics are stopped for safety, efficacy or other reasons or fail to meet their respective endpoints, our overall development plans, business, prospects, expected operating results and financial condition could be materially harmed and the value of our company could be negatively affected.

Outside the United States, our and our collaborators' ability to market a product is contingent upon receiving a marketing authorization from the appropriate regulatory authorities. This foreign regulatory approval process typically includes all of the risks associated with the FDA approval process described above and may also include additional risks. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country and may require us to perform additional testing and expend additional resources. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other countries or by the FDA.

Health care reform measures could impact the pricing and profitability of pharmaceuticals, and adversely affect the commercial viability of our products and drug candidates. Our ability to generate revenues will be diminished if we are unable to obtain an adequate level of reimbursement from private insurers, government insurance programs or other third party payors of health care costs, which could be affected by current and potential healthcare reform legislation.

Our ability to commercialize our current and any future approved products successfully will depend in part on the extent to which adequate reimbursement levels for the cost of our products and related treatment are obtained from

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third party payors, such as private insurers, government insurance programs, including Medicare and Medicaid, health maintenance organizations (HMOs) and other health care related organizations.

In recent years, through legislative and regulatory actions, the federal government has made substantial changes to various payment systems under the Medicare and other federal health care programs. Comprehensive reforms to the U.S. healthcare system were enacted, including changes to the methods for, and amounts of, Medicare reimbursement. While there is currently significant uncertainty regarding the implementation of some of these reforms or the scope of amended or additional reforms, the implementation of reforms could significantly reduce payments from Medicare and Medicaid. Reforms or other changes to these payment systems, may change the availability, methods and rates of reimbursements from Medicare, private insurers and other third-party payors for our current and any future approved products. Some of these changes and proposed changes could result in reduced reimbursement rates or in eliminating dual sources of payment, which could reduce the price that we or any of our collaborators or licensees receive for any products in the future, and which would adversely affect our business strategy, operations and financial results. Further federal and state proposals to regulate prices of pharmaceutical products and other health care reforms are possible, which could limit the prices that can be charged for any of our products and may further limit the commercial viability of our products and drug candidates. In certain foreign markets, pricing or profitability of prescription pharmaceuticals is subject to government control. If reimbursement for our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed. There may be future changes that result in reductions in current coverage and reimbursement levels for our current or any future approved products, and we cannot predict the scope of any future changes or the impact that those changes would have on our operations.

Third party payors are increasingly challenging the prices charged for medical products and services. Also, the trend toward managed health care in the United States, the organizations for which could control or significantly influence the purchase of health care services and products, as well as legislative and regulatory proposals to reform health care or reduce government insurance programs, may all result in lower prices for or rejection of our products. Adoption of our products by the medical community may be limited without adequate reimbursement for those products. Cost control initiatives may decrease coverage and payment levels for our products and, in turn, the price that we will be able to charge for any product. Our products may not be considered cost effective, and coverage and reimbursement may not be available or sufficient to allow us to sell our products on a profitable basis. We are unable to predict all changes to the coverage or reimbursement methodologies that will be applied by private or government payors to our current and any future approved products.

The continuing efforts of legislatures, health agencies and third party payors to contain or reduce the costs of health care, any denial of private or government payor coverage or inadequate reimbursement for our drug candidates could materially and adversely affect our business strategy, operations, future revenues and profitability, and the future revenues and profitability of our potential customers, suppliers, collaborators and licensees and the availability of capital. The same risks apply to our compounds developed and marketed by our collaborators, and our future potential milestone and royalty revenues could be affected in a similar manner.

We depend on our collaborators and licensees for the future development and commercialization of some of our drug candidates. Conflicts may arise between our collaborators and licensees and us, or our collaborators and licensees may choose to terminate their agreements with us, which may adversely affect our business.

We have licensed to Novartis rights to ruxolitinib outside of the United States and worldwide rights to our c MET inhibitor compounds and licensed to Lilly worldwide rights to baricitinib. We have also licensed to Pfizer our portfolio of CCR2 antagonist compounds. Under the terms of our agreements with these collaborators, we have no or limited control over the further clinical development of these drug candidates and any revenues we may receive if these drug candidates receive regulatory approval and are commercialized will depend primarily on the development

and commercialization efforts of others. While OLUMIANT (baricitinib) was approved by the European Commission in February 2017 for the treatment of moderate-to-severe rheumatoid arthritis in adult patients and by Japan's Ministry of Health, Labor and Welfare in July 2017 for the treatment of rheumatoid arthritis in patients with inadequate response to standard-of-care therapies, if the New Drug Application for baricitinib for the treatment of moderate-to-severe rheumatoid arthritis does not receive FDA approval, we will not receive future milestone payments or royalties related to that indication in the United States under our agreement with Lilly. In addition, even if baricitinib is approved by the FDA in this indication, delays in any

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such approval, or any label modifications or restrictions in connection with any approval by the FDA, European or other regulatory authorities, or the existence of other risks relating to approved drug products, including those described under "Risks Relating to Commercialization of Our Products," could delay the receipt of and reduce resulting potential royalty and milestone revenue from baricitinib.

Conflicts may arise with our collaborators and licensees if they pursue alternative technologies or develop alternative products either on their own or in collaboration with others as a means for developing treatments for the diseases that we have targeted. Competing products and product opportunities may lead our collaborators and licensees to withdraw their support for our drug candidates. Any failure of our collaborators and licensees to perform their obligations under our agreements with them or otherwise to support our drug candidates could negatively impact the development of our drug candidates, lead to our loss of potential revenues from product sales and milestones and delay our achievement, if any, of profitability. Additionally, conflicts may arise if, among other things, there is a dispute about the achievement and payment of a milestone amount or the ownership of intellectual property that is developed during the course of a collaborative relationship.

Our existing collaborative and license agreements can be terminated by our collaborators and licensees for convenience, among other circumstances. If any of our collaborators or licensees terminates its agreement with us, or terminates its rights with respect to certain indications or drug candidates, we may not be able to find a new collaborator for them, and our business could be adversely affected. Should an agreement be terminated before we have realized the benefits of the collaboration or license, our reputation could be harmed, we may not obtain revenues that we anticipated receiving, and our business could be adversely affected.

The success of our drug discovery and development efforts may depend on our ability to find suitable collaborators to fully exploit our capabilities. If we are unable to establish collaborations or if these future collaborations are unsuccessful in the development and commercialization of our drug candidates, our research, development and commercialization efforts may be unsuccessful, which could adversely affect our results of operations and financial condition.

An important element of our business strategy is to enter into collaborative or license arrangements with other parties, under which we license our drug candidates to those parties for development and commercialization or under which we study our drug candidates in combination with other parties' compounds or biologics. For example, in addition to our Novartis, Lilly and Pfizer collaborations, we have entered into clinical study relationships with respect to epacadostat and are evaluating strategic relationships with respect to several of our other programs. However, because collaboration and license arrangements are complex to negotiate, we may not be successful in our attempts to establish these arrangements. Also, we may not have drug candidates that are desirable to other parties, or we may be unwilling to license a drug candidate to a particular party because such party interested in it is a competitor or for other reasons. The terms of any such arrangements that we establish may not be favorable to us. Alternatively, potential collaborators may decide against entering into an agreement with us because of our financial, regulatory or intellectual property position or for scientific, commercial or other reasons. If we are not able to establish collaboration or license arrangements, we may not be able to develop and commercialize a drug product, which could adversely affect our business and our revenues.

We will likely not be able to control the amount and timing of resources that our collaborators or licensees devote to our programs or drug candidates. If our collaborators or licensees prove difficult to work with, are less skilled than we originally expected, do not devote adequate resources to the program, are unable to obtain regulatory approval of our drug candidates, pursue alternative technologies or develop alternative products, or do not agree with our approach to development or manufacturing of the drug candidate, the relationship could be unsuccessful. Our collaborations with respect to epacadostat involve the study of our collaborators' drugs used in combination with epacadostat on a number of indications or tumor types, many of which are the same across multiple collaborations. We cannot assure you that

potential conflicts will not arise or be alleged among these collaborations. If a business combination involving a collaborator or licensee and a third party were to occur, the effect could be to terminate or cause delays in development of a drug candidate.

If we fail to enter into additional licensing agreements or if these arrangements are unsuccessful, our business and operations might be adversely affected.

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In addition to establishing collaborative or license arrangements under which other parties license our drug candidates for development and commercialization or under which we study our drug candidates in combination with such parties' compounds or biologics, we may explore opportunities to develop our clinical pipeline by in-licensing drug candidates that fit within our focus on oncology, such as our collaborations with Agenus, Merus N.V., and Jiangsu Hengrui Medicine Co., Ltd., or explore additional opportunities to further develop and commercialize existing drug candidates in specific jurisdictions, such as our recent acquisition of the development and commercialization rights to ICLUSIG in certain countries. We may be unable to enter into any additional in-licensing agreements because suitable drug candidates that are within our expertise may not be available to us on terms that are acceptable to us or because competitors with greater resources seek to in-license the same drug candidates. Drug candidates that we would like to develop or commercialize may not be available to us because they are controlled by competitors who are unwilling to license the rights to the drug candidate to us. In addition, we may enter into license agreements that are unsuccessful and our business and operations might be adversely affected if we are unable to realize the expected economic benefits of a collaboration or other licensing arrangement, by the termination of a drug candidate and termination and winding down of the related license agreement, or due to other business or regulatory issues that may adversely affect a licensor's ability to continue to perform its obligations under an in-license agreement. As discussed above under "We depend on our collaborators and licensees for the future development and commercialization of some of our drug candidates. Conflicts may arise between our collaborators and licensees and us, or our collaborators and licensees may choose to terminate their agreements with us, which may adversely affect our business," conflicts or other issues may arise with our licensors. Those conflicts could result in delays in our plans to develop drug candidates or result in the expenditure of additional funds to resolve those conflicts that could have an adverse effect on our results of operations. We may also need to license drug delivery or other technology in order to continue to develop our drug candidates. If we are unable to enter into additional agreements to license drug candidates, drug delivery technology or other technology or if these arrangements are unsuccessful, our research and development efforts could be adversely affected.

Even if a drug candidate that we develop receives regulatory approval, we may decide not to commercialize it if we determine that commercialization of that product would require more money and time than we are willing to invest.

Even if any of our drug candidates receives regulatory approval, it could be subject to post regulatory surveillance, and may have to be withdrawn from the market or subject to restrictions if previously unknown problems occur. Regulatory agencies may also require additional clinical trials or testing, and the drug product may be recalled or may be subject to reformulation, additional studies, changes in labeling, warnings to the public and negative publicity. As a result, we may not continue to commercialize a product even though it has obtained regulatory approval. Further, we may decide not to continue to commercialize a product if the market does not accept the product because it is too expensive or because third parties such as insurance companies or Medicare have not approved it for substantial reimbursement. In addition, we may decide not to continue to commercialize a product if competitors develop and commercialize similar or superior products or have proprietary rights that preclude us from ultimately marketing our products.

Any approved drug product that we bring to the market may not gain market acceptance by physicians, patients, healthcare payors and others in the medical community.

Even if we are successful in gaining regulatory approval of any of our drug candidates in addition to JAKAFI or acquire rights to approved drug products in addition to ICLUSIG, we may not generate significant product revenues and we may not become profitable if these drug products do not achieve an adequate level of acceptance. Physicians may not recommend our drug products until longer term clinical data or other factors demonstrate the safety and efficacy of our drug products as compared to other alternative treatments. Even if the clinical safety and efficacy of our drug products is established, physicians may elect not to prescribe these drug products for a variety of reasons, including the reimbursement policies of government and other third party payors and the effectiveness of our

competitors in marketing their products.

Market acceptance of our drug products, if approved for commercial sale, will depend on a number of factors, including:

· the willingness and ability of patients and the healthcare community to use our drug products;

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- the ability to manufacture our drug products in sufficient quantities with acceptable quality and to offer our drug products for sale at competitive prices;
- the perception of patients and the healthcare community, including third party payors, regarding the safety, efficacy and benefits of our drug products compared to those of competing products or therapies;
- the label and promotional claims allowed by the FDA;
- the pricing and reimbursement of our drug products relative to existing treatments; and
- marketing and distribution support for our drug products.

We have limited capacity to conduct preclinical testing and clinical trials, and our resulting dependence on other parties could result in delays in and additional costs for our drug development efforts.

We have limited internal resources and capacity to perform preclinical testing and clinical trials. As part of our development strategy, we often hire clinical research organizations, or CROs, to perform preclinical testing and clinical trials for drug candidates. If the CROs that we hire to perform our preclinical testing and clinical trials do not meet deadlines, do not follow proper procedures, or a conflict arises between us and our CROs, our preclinical testing and clinical trials may take longer than expected, may cost more, may be delayed or may be terminated. If we were forced to find a replacement entity to perform any of our preclinical testing or clinical trials, we may not be able to find a suitable entity on favorable terms, or at all. Even if we were able to find another company to perform a preclinical test or clinical trial, the delay in the test or trial may result in significant additional expenditures. Events such as these may result in delays in our obtaining regulatory approval for our drug candidates or our ability to commercialize our products and could result in increased expenditures that would adversely affect our operating results.

We face significant competition for our drug discovery and development efforts, and if we do not compete effectively, our commercial opportunities will be reduced or eliminated.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Our drug discovery and development efforts may target diseases and conditions that are already subject to existing therapies or that are being developed by our competitors, many of which have substantially greater resources, larger research and development staffs and facilities, more experience in completing preclinical testing and clinical trials, and formulation, marketing and manufacturing capabilities. As a result of these resources, our competitors may develop drug products that render our products obsolete or noncompetitive by developing more effective drugs, developing their products more efficiently or pricing their products more competitively. Our ability to develop competitive products would be limited if our competitors succeeded in obtaining regulatory approvals for drug candidates more rapidly than we were able to or in obtaining patent protection or other intellectual property rights that limited our drug development efforts. Any drug products resulting from our research and development efforts, or from our joint efforts with collaborators or licensees, might not be able to compete successfully with our competitors' existing and future products, or obtain regulatory approval in the United States or elsewhere. The development of products or processes by our competitors with significant advantages over those that we are developing could harm our future revenues and profitability.

Our reliance on other parties to manufacture our drug products and drug candidates could result in a short supply of the drugs, delays in clinical trials or drug development, increased costs, and withdrawal or denial of a regulatory authority's approval.

We do not currently operate manufacturing facilities for clinical or commercial production of JAKAFI and our other drug candidates or for ICLUSIG. We currently hire third parties to manufacture the raw materials, active pharmaceutical ingredient, or API, and finished drug product of JAKAFI and our other drug candidates for clinical trials. Under our license agreement with ARIAD, we receive our supply of ICLUSIG from ARIAD. In addition, we

expect to continue to rely on third parties for the manufacture of commercial supplies of raw materials, API and finished drug product for any drugs that we successfully develop. We also hire third parties to package and label the finished product. The FDA requires that the raw materials, API and finished product for JAKAFI and our other drug candidates be manufactured

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according to its current Good Manufacturing Practices regulations and regulatory authorities in other countries have similar requirements. There are only a limited number of manufacturers that comply with these requirements. Failure to comply with current Good Manufacturing Practices and the applicable regulatory requirements of other countries in the manufacture of our drug candidates and products could result in the FDA or a foreign regulatory authority halting our clinical trials, withdrawing or denying regulatory approval of our drug product, enforcing product recalls or other enforcement actions, which could have a material adverse effect on our business.

We may not be able to obtain sufficient quantities of our drug candidates or any drug products we may develop if our designated manufacturers do not have the capacity or capability to manufacture them according to our schedule and specifications. Manufacturers of pharmaceutical products often encounter difficulties in production, especially in scaling up initial production. These problems include difficulties with production costs and yields, quality control and assurance and shortages of qualified personnel. In addition, we may not be able to arrange for our drug candidates or any drug products that we may develop to be manufactured by one of these parties on reasonable terms, if at all. We generally have a single source or a limited number of suppliers that are qualified to supply each of the API and finished product of JAKAFI and our other drug candidates and, in the case of JAKAFI, we only have a single source for its raw materials. If any of these suppliers were to become unable or unwilling to supply us with raw materials, API or finished product that complies with applicable regulatory requirements, we could incur significant delays in our clinical trials or interruption of commercial supply that could have a material adverse effect on our business. If we have promised delivery of a drug candidate or drug product and are unable to meet the delivery requirement due to manufacturing difficulties, our development programs could be delayed, we may have to expend additional sums in order to ensure that manufacturing capacity is available when we need it even if we do not use all of the manufacturing capacity, and our business and operating results could be harmed.

We may not be able to adequately manage and oversee the manufacturers we choose, they may not perform as agreed or they may terminate their agreements with us. Foreign manufacturing approval processes typically include all of the risks associated with the FDA approval process for manufacturing and may also include additional risks.

Two of our collaborations involve the manufacture of antibodies. Under our collaboration with Agenus, Agenus had primary responsibility for manufacturing activities, including selecting and monitoring third-party manufacturers. Under the February 2017 amendment to our collaboration agreement, we assumed primary responsibility for manufacturing activities, including selecting and monitoring third party manufacturers, of all products from royalty-bearing programs under the collaboration. Under our collaboration with Hengrui, Hengrui currently has primary responsibility for manufacturing activities, and we are in the process of transferring manufacturing activities to a third party contract manufacturing organization. Manufacturing antibodies and products containing antibodies is a more complex process than manufacturing small molecule drugs and subject to additional risks. The process of manufacturing antibodies and products containing antibodies is highly susceptible to product loss due to contamination, equipment failure or 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, viral 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.

If we fail to comply with the extensive legal and regulatory requirements affecting the health care industry, we could face increased costs, penalties and a loss of business.

Our activities, and the activities of our collaborators, partners and third party providers, are subject to extensive government regulation and oversight both in the United States and in foreign jurisdictions. The FDA and comparable agencies in other jurisdictions directly regulate many of our most critical business activities, including the conduct of

preclinical and clinical studies, product manufacturing, advertising and promotion, product distribution, adverse event reporting and product risk management. States increasingly have been placing greater restrictions on the marketing practices of healthcare companies. In addition, pharmaceutical and biotechnology companies have been the target of lawsuits and investigations alleging violations of government regulations, including claims asserting submission of incorrect pricing information, impermissible off label promotion of pharmaceutical products, payments intended to

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influence the referral of federal or state healthcare business, submission of false claims for government reimbursement, antitrust violations, violations of the U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act and similar anti bribery or anti corruption laws, or violations related to environmental matters. There is also enhanced scrutiny of company-sponsored patient assistance programs, including insurance premium and co-pay assistance programs and donations to third-party charities that provide such assistance. Violations of governmental regulation by us, our vendors or donation recipients may be punishable by criminal and civil sanctions, including fines and civil monetary penalties and exclusion from participation in government programs, including Medicare and Medicaid. In addition to penalties for violation of laws and regulations, we could be required to repay amounts we received from government payors, or pay additional rebates and interest if we are found to have miscalculated the pricing information we have submitted to the government. Actions taken by federal or local governments, legislative bodies and enforcement agencies with respect to these legal and regulatory compliance matters could also result in reduced demand for our products, reduced coverage of our products by health care payors, or both. We cannot ensure that our compliance controls, policies, and procedures will in every instance protect us from acts committed by our employees, collaborators, partners or third party providers that would violate the laws or regulations of the jurisdictions in which we operate. Whether or not we have complied with the law, an investigation into alleged unlawful conduct could increase our expenses, damage our reputation, divert management time and attention and adversely affect our business. Risks relating to compliance with laws and regulations may be heightened as we continue to expand our global operations and enter new therapeutic areas with different patient populations, which due to different product distribution methods, marketing programs or patient assistance programs may result in additional regulatory burdens and obligations.

As our drug discovery and development operations are conducted at our headquarters in Wilmington, Delaware, the loss of access to this facility would negatively impact our business.

Our facility in Wilmington, Delaware is our headquarters and is also where we conduct all of our drug discovery, research, development and marketing activities. In addition, natural disasters or actions of activists opposed to aspects of pharmaceutical research may disrupt our experiments or our ability to access or use our facility. The loss of access to or use of our Wilmington, Delaware, facility, either on a temporary or permanent basis would result in an interruption of our business and, consequently, would adversely affect our overall business.

We depend on key employees in a competitive market for skilled personnel, and the loss of the services of any of our key employees or our inability to attract and retain additional personnel would affect our ability to expand our drug discovery and development programs and achieve our objectives.

We are highly dependent on the members of our executive management team and principal members of our commercial, development, medical, operations and scientific staff. We experience intense competition for qualified personnel. Our future success also depends in part on the continued service of our executive management team and key personnel and our ability to recruit, train and retain essential personnel for our drug discovery and development programs, and for our medical affairs and commercialization activities. If we lose the services of any of these people or if we are unable to recruit sufficient qualified personnel, our research and product development goals, and our commercialization efforts could be delayed or curtailed. We do not maintain “key person” insurance on any of our employees.

If we fail to manage our growth effectively, our ability to develop and commercialize products could suffer.

We expect that if our drug discovery efforts continue to generate drug candidates, our clinical drug candidates continue to progress in development, and we continue to build our development, medical and commercial organizations, we will require significant additional investment in personnel, management and resources. Our ability to achieve our research, development and commercialization objectives depends on our ability to respond effectively

to these demands and expand our internal organization, systems, controls and facilities to accommodate additional anticipated growth. If we are unable to manage our growth effectively, our business could be harmed and our ability to execute our business strategy could suffer.

We may acquire businesses or assets, form joint ventures or make investments in other companies that may be unsuccessful, divert our management’s attention and harm our operating results and prospects.

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As part of our business strategy, we may pursue additional acquisitions of what we believe to be complementary businesses or assets or seek to enter into joint ventures. We also may pursue strategic alliances in an effort to leverage our existing infrastructure and industry experience to expand our product offerings or distribution, or make investments in other companies. For example, in June 2016, we completed the acquisition of the European operations of ARIAD and obtained the exclusive license to develop and commercialize ICLUSIG in Europe and other countries. The success of our acquisitions, joint ventures, strategic alliances and investments will depend on our ability to identify, negotiate, complete and, in the case of acquisitions, integrate those transactions and, if necessary, obtain satisfactory debt or equity financing to fund those transactions. We may not realize the anticipated benefits of any acquisition, joint venture, strategic alliance or investment. We may not be able to integrate acquisitions successfully into our existing business, maintain the key business relationships of businesses we acquire, or retain key personnel of an acquired business, and we could assume unknown or contingent liabilities or incur unanticipated expenses. Integration of acquired companies or businesses also may require management resources that otherwise would be available for ongoing development of our existing business. Any acquisitions or investments made by us also could result in significant write-offs or the incurrence of debt and contingent liabilities, any of which could harm our operating results. For example, in the years ended December 31, 2016 and December 31, 2015, we recorded unrealized losses related to our investment in Agenus Inc., and we may in the future experience additional losses related to our investments. In addition, if we choose to issue shares of our stock as consideration for any acquisition, dilution to our stockholders could result.

Risks associated with the expansion of our operations outside of the United States could adversely affect our business.

Our acquisition of ARIAD's European operations significantly expanded our operations in Europe, and we plan to continue to expand our operations and conduct certain development activities outside of the United States. We have limited experience with conducting activities outside of the United States. International operations and business expansion plans are subject to numerous additional risks, including:

- multiple, conflicting and changing laws and regulations such as tax laws, privacy regulations, tariffs, export and import restrictions, employment, immigration and labor laws, regulatory requirements, and other governmental approvals, permits and licenses;
- difficulties in staffing and managing foreign operations and difficulties in connection with assimilating and integrating the ARIAD operations and personnel, and any other operations and personnel we might acquire into our company;
- risks associated with obtaining and maintaining, or the failure to obtain or maintain, regulatory approvals for the sale or use of our products in various countries;
- complexities associated with managing government payor systems, multiple payor reimbursement regimes or patient self pay systems;
- financial risks, such as longer payment cycles, difficulty obtaining financing in foreign markets, difficulty enforcing contracts and intellectual property rights, difficulty collecting accounts receivable and exposure to foreign currency exchange rate fluctuations;
- general political and economic conditions in the countries in operate, including terrorism and political unrest, curtailment of trade and other business restrictions, and uncertainties associated with the future relationship between the United Kingdom and the European Union; and
- regulatory and compliance risks that relate to maintaining accurate information and control over activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act, its books and records provisions or its anti bribery provisions, or similar anti bribery or anti corruption laws and regulations.

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Although we conducted due diligence of ARIAD's European operations prior to the acquisition, we may discover or identify deficiencies or non-compliance with such laws and regulations as we complete the integration of the ARIAD business and conduct our European operations. Any of the risks described above, if encountered, could significantly increase our costs of operating internationally, prevent us from operating in certain jurisdictions, or otherwise significantly harm our future international expansion and operations, which could have a material adverse effect on our business, financial condition and results of operations.

If product liability lawsuits are brought against us, we could face substantial liabilities and may be required to limit commercialization of our products and our results of operations could be harmed.

In addition to the risks described above under "—Risks Relating to Commercialization of Our Products—If the use of our products harms patients, or is perceived to harm patients even when such harm is unrelated to our products, our regulatory approvals could be revoked or otherwise negatively impacted or we could be subject to costly and damaging product liability claims," the conduct of clinical trials of medical products that are intended for human use entails an inherent risk of product liability. If any product that we or any of our collaborators or licensees develops causes or is alleged to cause injury during clinical trials or commercialization, we may be held liable. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities, including substantial damages to be paid to the plaintiffs and legal costs, or we may be required to limit further development and commercialization of our products. Additionally, any product liability lawsuit could cause injury to our reputation, participants and investigators to withdraw from clinical trials, and potential collaborators or licensees to seek other partners, any of which could impact our results of operations.

Our product liability insurance policy may not fully cover our potential liabilities. In addition, we may determine that we should increase our coverage, and this insurance may be prohibitively expensive to us or our collaborators or licensees and may not fully cover our potential liabilities. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the development or commercialization of our drug candidates and products.

Because our activities involve the use of hazardous materials, we may be subject to claims relating to improper handling, storage or disposal of these materials that could be time consuming and costly.

We are subject to various environmental, health and safety laws and regulations governing, among other things, the use, handling, storage and disposal of regulated substances and the health and safety of our employees. Our research and development processes involve the controlled use of hazardous and radioactive materials and biological waste resulting in the production of hazardous waste products. We cannot completely eliminate the risk of accidental contamination or discharge and any resultant injury from these materials. If any injury or contamination results from our use or the use by our collaborators or licensees of these materials, we may be sued and our liability may exceed our insurance coverage and our total assets. Further, we may be required to indemnify our collaborators or licensees against all damages and other liabilities arising out of our development activities or products produced in connection with these collaborations or licenses. Compliance with the applicable environmental and workplace laws and regulations is expensive. Future changes to environmental, health, workplace and safety laws could cause us to incur additional expense or may restrict our operations or impair our research, development and production efforts.

RISKS RELATING TO OUR FINANCIAL RESULTS

We may incur losses in the future and we may not achieve or maintain profitability in the future.

Due to historical net losses, we had an accumulated deficit of $1.8 billion as of September 30, 2017. We intend to continue to spend significant amounts on our efforts to discover and develop drugs. As a result, we may incur losses

for the year ending December 31, 2017 and in future periods as well.

We anticipate that our drug discovery and development efforts and related expenditures will increase as we focus on the studies, including preclinical tests and clinical trials prior to seeking regulatory approval, that are required before we can sell a drug product.

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The development of drug products will require us to spend significant funds on research, development, testing, obtaining regulatory approvals, manufacturing and marketing. To date, we do not have any drug products that have generated significant revenues other than from sales of JAKAFI and we cannot assure you that we will generate significant revenues from the drug candidates that we license or develop, including ICLUSIG, for several years, if ever.

We cannot be certain whether or when we will achieve profitability because of the significant uncertainties relating to our ability to generate commercially successful drug products. Even if we are successful in obtaining regulatory approvals for manufacturing and commercializing drug products in addition to JAKAFI and ICLUSIG, we may incur losses if our drug products do not generate significant revenues. If we achieve profitability, we may not be able to sustain or increase profitability.

We may need additional capital in the future. If we are unable to generate sufficient funds from operations, the capital markets may not permit us to raise additional capital at the time that we require it, which could result in limitations on our research and development or commercialization efforts or the loss of certain of our rights in our technologies or drug candidates.

Our future funding requirements will depend on many factors and we anticipate that we may need to raise additional capital to fund our business plan and research and development efforts going forward and to repay our indebtedness.

Additional factors that may affect our future funding requirements include:

- the amount of revenues generated from our business activities;
- any changes in the breadth of our research and development programs;
- the results of research and development, preclinical testing and clinical trials conducted by us or our current or future collaborators or licensees, if any;
- our exercise of any co development options with collaborators that may require us to fund future development;
- the acquisition of businesses, technologies, or drug candidates, or the licensing of technologies or drug candidates, if any;
- costs for future facility requirements;
- our ability to maintain and establish new corporate relationships and research collaborations;
- competing technological and market developments;
- the time and costs involved in filing, prosecuting, defending and enforcing patent and intellectual property claims;
- the receipt of contingent licensing or milestone fees or royalties on product sales from our current or future collaborative and license arrangements, if established; and
- the timing of regulatory approvals, if any.

If we require additional capital at a time when investment in companies such as ours, or in the marketplace generally, is limited due to the then prevailing market or other conditions, we may have to scale back our operations, eliminate one or more of our research or development programs, or attempt to obtain funds by entering into an agreement with a collaborator or licensee that would result in terms that are not favorable to us or relinquishing our rights in certain

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of our proprietary technologies or drug candidates. If we are unable to raise funds at the time that we desire or at any time thereafter on acceptable terms, we may not be able to continue to develop our drug candidates. The sale of equity or additional convertible debt securities in the future may be dilutive to our stockholders and may provide for rights, preferences or privileges senior to those of our holders of common stock, and debt financing arrangements may require us to pledge certain assets or enter into covenants that could restrict our operations or our ability to incur further indebtedness.

Our marketable securities and long term investments are subject to risks that could adversely affect our overall financial position.

We invest our cash in accordance with an established internal policy and customarily in instruments, corporate bonds and money market funds which historically have been highly liquid and carried relatively low risk. In recent periods, similar types of investments and money market funds have experienced losses in value or liquidity issues that differ from their historical pattern.

Should a portion of our cash or marketable securities lose value or have their liquidity impaired, it could adversely affect our overall financial position by imperiling our ability to fund our operations and forcing us to seek additional financing sooner than we would otherwise. Such financing, if available, may not be available on commercially attractive terms.

As discussed under “Other Risks Relating to Our Business— We may acquire businesses or assets, form joint ventures or make investments in other companies that may be unsuccessful, divert our management’s attention and harm our operating results and prospects,” any investments that we may make in companies with which we have strategic alliances, such as Agenus and Merus, could result in our recognition of losses on those investments. In addition, to the extent we may seek to sell or otherwise monetize those investments, we may not be able to do so at our desired price or valuation levels, or at all, due to the limited liquidity of some or all of those investments.

Any loss in value of our long term investments could adversely affect our financial position on the consolidated balance sheets and consolidated statements of operations.

Our current revenues are derived from JAKAFI and ICLUSIG product sales, JAKAVI product royalties, collaborations and from licensing our intellectual property. If we are unable to achieve milestones, develop products or renew or enter into new collaborations, our revenues may decrease, and future milestone and royalty payments may not contribute significantly to revenues for several years, and may never result in revenues.

We derived substantially all of our revenues for the three and nine months ended September 30, 2017 from JAKAFI and ICLUSIG product revenues, JAKAVI product royalties and our collaborations and licensing our intellectual property to others. Future revenues from research and development collaborations depend upon continuation of the collaborations, the achievement of milestones and royalties we earn from any future products developed from our research. If we are unable to successfully achieve milestones or our collaborators fail to develop successful products, we will not earn the future revenues contemplated under our collaborative agreements. For example, delays in or other limitations with respect to the approval of baricitinib for the treatment of moderate-to-severe rheumatoid arthritis, or the failure to obtain such approval, as discussed under “—We depend on our collaborators and licensees for the future development and commercialization of some of our drug candidates. Conflicts may arise between our collaborators and licensees and us, or our collaborators and licensees may choose to terminate their agreements with us, which may adversely affect our business.” would affect potential future royalty and milestone revenue.

RISKS RELATING TO INTELLECTUAL PROPERTY AND LEGAL MATTERS

If we are subject to arbitration, litigation and infringement claims, they could be costly and disrupt our drug discovery and development efforts.

The technology that we use to make and develop our drug products, the technology that we incorporate in our products, and the products we are developing may be subject to claims that they infringe the patents or proprietary rights of others. The success of our drug discovery and development efforts will also depend on our ability to develop new

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compounds, drugs and technologies without infringing or misappropriating the proprietary rights of others. We are aware of patents and patent applications filed in certain countries claiming intellectual property relating to some of our drug discovery targets and drug candidates. While the validity of issued patents, patentability of pending patent applications and applicability of any of them to our programs are uncertain, if any of these patents are asserted against us or if we choose to license any of these patents, our ability to commercialize our products could be harmed or the potential return to us from any product that may be successfully commercialized could be diminished.

From time to time we have received, and we may in the future receive, notices from third parties offering licenses to technology or alleging patent, trademark, or copyright infringement, claims regarding trade secrets or other contract claims. Receipt of these notices could result in significant costs as a result of the diversion of the attention of management from our drug discovery and development efforts. Parties sending these notices may have brought and in the future may bring litigation against us or seek arbitration relating to contract claims.

We may be involved in future lawsuits or other legal proceedings alleging patent infringement or other intellectual property rights or contract violations. In addition, litigation or other legal proceedings may be necessary to:

· assert claims of infringement;
· enforce our patents or trademarks;
· protect our trade secrets or know how; or
· determine the enforceability, scope and validity of the proprietary rights of others.

We may be unsuccessful in defending or pursuing these lawsuits, claims or other legal proceedings. Regardless of the outcome, litigation or other legal proceedings can be very costly and can divert management's efforts. An adverse determination may subject us to significant liabilities or require us or our collaborators or licensees to seek licenses to other parties' patents or proprietary rights. We or our collaborators or licensees may also be restricted or prevented from manufacturing or selling a drug or other product that we or they develop. Further, we or our future collaborators or licensees may not be able to obtain any necessary licenses on acceptable terms, if at all. If we are unable to develop non infringing technology or license technology on a timely basis or on reasonable terms, our business could be harmed.

We may be unable to adequately protect or enforce our proprietary information, which may result in its unauthorized use, a loss of revenue under a collaboration agreement or loss of sales to generic versions of our products or otherwise reduce our ability to compete in developing and commercializing products.

Our business and competitive position depends in significant part upon our ability to protect our proprietary technology, including any drug products that we create. Despite our efforts to protect this information, unauthorized parties may attempt to obtain and use information that we regard as proprietary. For example, one of our collaborators may disclose proprietary information pertaining to our drug discovery efforts. In addition, while we have filed numerous patent applications with respect to ruxolitinib and our drug candidates in the United States and in foreign countries, our patent applications may fail to result in issued patents. In addition, because patent applications can take several years to issue as patents, there may be pending patent applications of others that may later issue as patents that cover some aspect of ruxolitinib and our drug candidates. Our existing patents and any future patents we may obtain may not be broad enough to protect our products or all of the potential uses of our products, or otherwise prevent others from developing competing products or technologies. In addition, our patents may be challenged and invalidated or may fail to provide us with any competitive advantages if, for example, others were first to invent or first to file a patent application for the technologies and products covered by our patents. As noted above under "—Risks Relating to Commercialization of Our Products—Competition for our products could potentially harm our business and result in a decrease in our revenue," a potential generic drug company competitor has challenged certain patents relating to JAKAFI.

Additionally, when we do not control the prosecution, maintenance and enforcement of certain important intellectual property, such as a drug candidate in licensed to us or subject to a collaboration with a third party, the protection of the intellectual property rights may not be in our hands. If we do not control the intellectual property rights in licensed

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to us with respect to a drug candidate and the entity that controls the intellectual property rights does not adequately protect those rights, our rights may be impaired, which may impact our ability to develop, market and commercialize the in licensed drug candidate.

Our means of protecting our proprietary rights may not be adequate, and our competitors may:

· independently develop substantially equivalent proprietary information, products and techniques;
· otherwise gain access to our proprietary information; or
· design around patents issued to us or our other intellectual property.

We pursue a policy of having our employees, consultants and advisors execute proprietary information and invention agreements when they begin working for us. However, these agreements may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure. If we fail to maintain trade secret and patent protection, our potential, future revenues may be decreased.

If the effective term of our patents is decreased due to changes in the United States patent laws or if we need to refile some of our patent applications, the value of our patent portfolio and the revenues we derive from it may be decreased.

The value of our patents depends in part on their duration. A shorter period of patent protection could lessen the value of our rights under any patents that we obtain and may decrease the revenues we derive from our patents. The United States patent laws were amended in 1995 to change the term of patent protection from 17 years from patent issuance to 20 years from the earliest effective filing date of the application. Because the time from filing to issuance of biotechnology applications may be more than three years depending on the subject matter, a 20 year patent term from the filing date may result in substantially shorter patent protection.

Additionally, United States patent laws were amended in 2011 with the enactment of the America Invents Act and third parties are now able to challenge the validity of issued U.S. patents through various review proceedings; thus rendering the validity of U.S. patents more uncertain. We may be obligated to participate in review proceedings to determine the validity of our U.S. patents. We cannot predict the ultimate outcome of these proceedings, the conduct of which could result in substantial costs and diversion of our efforts and resources. If we are unsuccessful in these proceedings some or all of our claims in the patents may be narrowed or invalidated and the patent protection for our products and drug candidates in the United States could be substantially shortened. Further, if all of the patents covering one of our products are invalidated, the FDA could approve requests to manufacture a generic version of that product prior to the expiration date of those patents.

Other changes in the United States patent laws or changes in the interpretation of patent laws could diminish the value of our patents or narrow the scope of our patent protection. For example, the Supreme Court of the United States recently ruled that isolated DNA sequences cannot be patented. Although we no longer receive significant revenues generated from our former information products business, the majority of our gene patent portfolio from that business consists of patents on isolated DNA sequences, and this ruling limits our ability to derive additional revenues from our gene patent portfolio. Additionally, the Supreme Court recently resolved a split among the circuit courts of appeals regarding antitrust challenges to settlements of patent infringement lawsuits under the Hatch Waxman Act between brand name drug companies and generic drug companies. The Court rejected the “scope of the patent” test and ruled that settlements involving “reverse payments” from brand name drug companies to generic drug companies should be analyzed under the rule of reason. This ruling may create uncertainty and make it more difficult to settle patent litigation if a company seeking to manufacture a generic version of one of our products challenges the patents covering that product prior to the expiration date of those patents.

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International patent protection is particularly uncertain and costly, and our involvement in opposition proceedings in foreign countries may result in the expenditure of substantial sums and management resources.

Biotechnology and pharmaceutical patent law outside the United States is even more uncertain and costly than in the United States and is currently undergoing review and revision in many countries. Further, the laws of some foreign countries may not protect our intellectual property rights to the same extent as United States laws. For example, certain countries do not grant patent claims that are directed to the treatment of humans. We have participated, and may in the future participate, in opposition proceedings to determine the validity of our foreign patents or our competitors' foreign patents, which could result in substantial costs and diversion of our efforts. For example, there is a patent opposition proceeding in India against our Indian patent that covers the composition of matter and use of certain Janus Kinase inhibitors, including ruxolitinib phosphate, for the treatment of myeloid proliferative disorders, cancer, immune related diseases, skin disorders, and other diseases. Successful challenges to our patent or other intellectual property rights through these proceedings could result in a loss of rights in the relevant jurisdiction and allow third parties to use our proprietary technologies without a license from us or our collaborators, which may also result in loss of future royalty payments. In addition, successful challenges may jeopardize or delay our ability to enter into new collaborations or commercialize potential products, which could harm our business and results of operations.

RISKS RELATING TO INFORMATION TECHNOLOGY AND DATA PRIVACY

Significant disruptions of information technology systems, breaches of data security, or unauthorized disclosures of sensitive data or personally identifiable information or individually identifiable health information could adversely affect our business, and could subject us to liability or reputational damage.

Our business is increasingly dependent on critical, complex, and interdependent information technology (IT) systems, including Internet-based systems, some of which are managed or hosted by third parties, to support business processes as well as internal and external communications. The size and complexity of our IT systems make us potentially vulnerable to IT system breakdowns, malicious intrusion, and computer viruses, which may result in the impairment of our ability to operate our business effectively.

In addition, our systems and the systems of our third-party providers and collaborators are potentially vulnerable to data security breaches which may expose sensitive data to unauthorized persons or to the public. Such data security breaches could lead to the loss of confidential information, trade secrets or other intellectual property, or could lead to the public exposure of personal information (including personally identifiable information or individually identifiable health information) of our employees, clinical trial patients, customers, business partners, and others. Data security breaches could also result in loss of clinical trial data or damage to the integrity of that data. In addition, the increased use of social media by our employees and contractors could result in inadvertent disclosure of sensitive data or personal information, including but not limited to, confidential information, trade secrets and other intellectual property.

Any such disruption or security breach, as well as any action by us or our employees or contractors that might be inconsistent with the rapidly evolving data privacy and security laws and regulations applicable within the United States and elsewhere where we conduct business, could result in enforcement actions by U.S. states, the U.S. Federal government or foreign governments, liability or sanctions under data privacy laws that protect personally identifiable information, regulatory penalties, other legal proceedings such as but not limited to private litigation, the incurrence of significant remediation costs, disruptions to our operations and collaborations, and damage to our reputation, which could harm our business and operations. Because of the rapidly moving nature of technology and the increasing sophistication of cybersecurity threats, our measures to prevent, respond to and minimize such risks may be unsuccessful.

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Increasing use of social media could give rise to liability, breaches of data security, or reputational damage.

We and our employees are increasingly utilizing social media tools as a means of communication both internally and externally. Despite our efforts to monitor evolving social media communication guidelines and comply with applicable rules, there is risk that the use of social media by us or our employees to communicate about our products or business may cause us to be found in violation of applicable requirements. In addition, our employees may knowingly or inadvertently make use of social media in ways that may not comply with our social media policy or other legal or contractual requirements, which may give rise to liability, lead to the loss of trade secrets or other intellectual property, or result in public exposure of personal information of our employees, clinical trial patients, customers, and others. Furthermore, negative posts or comments about us or our products in social media could seriously damage our reputation, brand image, and goodwill.

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Item 6. Exhibits

Exhibit Number	Description of Document
31.1*	Rule 13a-14(a) Certification of Chief Executive Officer
31.2*	Rule 13a-14(a) Certification of Chief Financial Officer
32.1**	Statement of the Chief Executive Officer under Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350)
32.2**	Statement of the Chief Financial Officer under Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350)
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Presentation Linkbase Document
101.DEF*	XBRL Taxonomy Definition Linkbase Document

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* Filed herewith.

** In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release No. 34-47986, the certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Form 10-Q and will not be deemed “filed” for purposes of Section 18 of the Exchange Act. Such certifications will not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act.

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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.

INCYTE CORPORATION

Dated: October 31, 2017 By: /s/ HERVÉ HOPPENOT
Hervé Hoppenot
Chairman, President, and Chief Executive Officer
(Principal Executive Officer)

Dated: October 31, 2017 By: /s/ DAVID W. GRYSKA
David W. Gryska
Chief Financial Officer
(Principal Financial Officer)