
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended June 30, 2023

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 No. 0-19731

GILEAD SCIENCES, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of Incorporation or Organization)

94-3047598
(IRS Employer Identification No.)

333 Lakeside Drive, Foster City, California 94404
(Address of principal executive offices) (Zip Code)
650-574-3000
(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value, \$0.001 per share	GILD	The Nasdaq Global Select Market

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 every Interactive Data File required to be submitted 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 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 ☐
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 ☒

Number of shares outstanding of the issuer's common stock, par value \$0.001 per share, as of July 31, 2023: 1,246,014,353

GILEAD SCIENCES, INC.

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We own or have rights to various trademarks and trade names used in our business, including the following: GILEAD®, GILEAD SCIENCES®, KITE™, AMBISOME®, ATRIPLA®, BIKTARVY®, CAYSTON®, COMPLERA®, DESCOVY®, DESCOVY FOR PREP®, EMTRIVA®, EPCLUSA®, EVIPLERA®, GENVOYA®, HARVONI®, HEPCLUDEX®, HEPSERA®, JYSELECA®, LETAIRIS®, ODEFSEY®, RANEXA®, SOVALDI®, STRIBILD®, SUNLENCA®, TECARTUS®, TRODELVY®, TRUVADA®, TRUVADA FOR PREP®, TYBOST®, VEKLURY®, VEMLIDY®, VIREAD®, VOSEVI®, YESCARTA® and ZYDELIG®. This report also refers to trademarks, service marks and trade names of other companies, which are the property of their respective owners.

Certain amounts and percentages in this Quarterly Report on Form 10-Q may not sum or recalculate due to rounding.

This Quarterly Report on Form 10-Q, including Part I, Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations and Part II, Item 1A. Risk Factors, contains forward-looking statements regarding future events and our future results that are subject to the safe harbors created under the Securities Act of 1933, as amended, and the Securities Exchange Act of 1934, as amended. Words such as "expect," "anticipate," "target," "goal," "project," "hope," "intend," "plan," "believe," "seek," "estimate," "continue," "may," "could," "should," "might," "forecast" and variations of such words and similar expressions are intended to identify such forward-looking statements. In addition, any statements other than statements of historical fact are forward-looking statements, including statements regarding overall trends; operating cost and revenue trends; liquidity and capital needs; plans and expectations with respect to products, product candidates, corporate strategy, business and operations, financial projections and the use of capital; collaboration and licensing arrangements; patent protection and estimated loss of exclusivity for our products and product candidates; ongoing litigation and investigation matters; and other statements of expectations, beliefs, future plans and strategies, anticipated events or trends and similar expressions.

We have based these forward-looking statements on our current expectations about future events. These statements are not guarantees of future performance and involve risks, uncertainties and assumptions that are difficult to predict. Our actual results may differ materially from those suggested by these forward-looking statements for various reasons, including those identified in Part II, Item 1A. Risk Factors. Given these risks and uncertainties, you are cautioned not to place undue reliance on forward-looking statements. The forward-looking statements included in this report are made only as of the date hereof unless otherwise specified. Except as required under federal securities laws and the rules and regulations of U.S. Securities and Exchange Commission, we do not undertake, and specifically decline, any obligation to update any of these statements or to publicly announce the results of any revisions to any forward-looking statements after the distribution of this report, whether as a result of new information, future events, changes in assumptions or otherwise. In evaluating our business, you should carefully consider the risks described in Part II, Item 1A. Risk Factors of this Quarterly Report on Form 10-Q. Any of the risks contained herein could materially and adversely affect our business, results of operations and financial condition.

PART I. FINANCIAL INFORMATION

Item 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

GILEAD SCIENCES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited)

(in millions, except per share amounts)	June 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 5,704	\$ 5,412
Short-term marketable debt securities	963	973
Accounts receivable, net	4,229	4,777
Inventories	1,633	1,507
Prepaid and other current assets	1,757	1,774
Total current assets	14,287	14,443
Property, plant and equipment, net	5,540	5,475
Long-term marketable debt securities	1,334	1,245
Intangible assets, net	27,750	28,894
Goodwill	8,314	8,314
Other long-term assets	5,113	4,800
Total assets	\$ 62,337	\$ 63,171
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 622	\$ 905
Accrued rebates	3,494	3,479
Other current liabilities	5,810	4,580
Current portion of long-term debt and other obligations, net	4,037	2,273
Total current liabilities	13,964	11,237
Long-term debt, net	21,209	22,957
Long-term income taxes payable	2,610	3,916
Deferred tax liability	2,106	2,673
Other long-term obligations	1,354	1,179
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock, par value \$0.001 per share; 5 shares authorized; none outstanding	—	—
Common stock, par value \$0.001 per share; 5,600 shares authorized; 1,247 shares issued and outstanding	1	1
Additional paid-in capital	6,008	5,550
Accumulated other comprehensive income	10	2
Retained earnings	15,138	15,687
Total Gilead stockholders' equity	21,158	21,240
Noncontrolling interest	(64)	(31)
Total stockholders' equity	21,094	21,209
Total liabilities and stockholders' equity	\$ 62,337	\$ 63,171

See accompanying notes.

GILEAD SCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF INCOME
(unaudited)

(in millions, except per share amounts)	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenues:				
Product sales	\$ 6,564	\$ 6,138	\$ 12,870	\$ 12,672
Royalty, contract and other revenues	35	122	81	178
Total revenues	6,599	6,260	12,951	12,850
Costs and expenses:				
Cost of goods sold	1,442	1,442	2,843	2,866
Research and development expenses	1,407	1,102	2,854	2,280
Acquired in-process research and development expenses	236	330	717	338
In-process research and development impairment	—	—	—	2,700
Selling, general and administrative expenses	1,849	1,357	3,168	2,440
Total costs and expenses	4,934	4,231	9,581	10,624
Operating income	1,665	2,029	3,370	2,226
Interest expense	(230)	(242)	(459)	(480)
Other income (expense), net	152	(284)	(22)	(395)
Income before income taxes	1,588	1,503	2,888	1,351
Income tax expense	(549)	(368)	(865)	(204)
Net income	1,039	1,135	2,024	1,147
Net loss attributable to noncontrolling interest	6	9	32	16
Net income attributable to Gilead	\$ 1,045	\$ 1,144	\$ 2,055	\$ 1,163
Basic earnings per share attributable to Gilead	\$ 0.84	\$ 0.91	\$ 1.65	\$ 0.93
Shares used in basic earnings per share attributable to Gilead calculation	1,249	1,256	1,249	1,255
Diluted earnings per share attributable to Gilead	\$ 0.83	\$ 0.91	\$ 1.63	\$ 0.92
Shares used in diluted earnings per share attributable to Gilead calculation	1,258	1,260	1,260	1,261

See accompanying notes.

GILEAD SCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(unaudited)

(in millions)	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Net income	\$ 1,039	\$ 1,135	\$ 2,024	\$ 1,147
Other comprehensive income, net:				
Net foreign currency translation gain (loss)	37	(26)	32	(21)
Available-for-sale debt securities:				
Net unrealized gain (loss), net of tax impact of \$0, \$0, \$0 and \$0, respectively	(3)	(12)	6	(31)
Reclassifications to net income, net of tax impact of \$0, \$0, \$0 and \$0, respectively	1	1	1	1
Net change	(2)	(11)	7	(30)
Cash flow hedges:				
Net unrealized gain (loss), net of tax impact of \$1, \$13, \$0 and \$16, respectively	5	90	(1)	114
Reclassification to net income, net of tax impact of \$1, \$5, \$4 and \$8, respectively	(9)	(39)	(29)	(59)
Net change	(4)	51	(30)	55
Other comprehensive income, net	31	14	9	4
Comprehensive income, net	1,070	1,149	2,032	1,151
Comprehensive loss attributable to noncontrolling interest, net	6	9	32	16
Comprehensive income attributable to Gilead, net	<u>\$ 1,076</u>	<u>\$ 1,158</u>	<u>\$ 2,064</u>	<u>\$ 1,167</u>

See accompanying notes.

GILEAD SCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(unaudited)

Three Months Ended June 30, 2023								
(in millions, except per share amounts)	Gilead Stockholders' Equity							
	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Retained Earnings	Noncontrolling Interest	Total Stockholders' Equity	
	Shares	Amount						
Balance as of March 31, 2023	1,248	\$ 1	\$ 5,793	\$ (20)	\$ 15,223	\$ (58)	\$ 20,939	
Net income (loss)	—	—	—	—	1,045	(6)	1,039	
Other comprehensive income, net	—	—	—	31	—	—	31	
Issuances under equity incentive plans	2	—	23	—	—	—	23	
Stock-based compensation	—	—	198	—	—	—	198	
Repurchases of common stock under repurchase programs (\$79.68 average price per share)	(2)	—	(7)	—	(143)	—	(150)	
Repurchases of common stock for employee tax withholding under equity incentive plans and other	—	—	—	—	(33)	—	(33)	
Dividends declared (\$0.75 per share)	—	—	—	—	(954)	—	(954)	
Balance as of June 30, 2023	1,247	\$ 1	\$ 6,008	\$ 10	\$ 15,138	\$ (64)	\$ 21,094	

Six Months Ended June 30, 2023								
(in millions, except per share amounts)	Gilead Stockholders' Equity							
	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Retained Earnings	Noncontrolling Interest	Total Stockholders' Equity	
	Shares	Amount						
Balance as of December 31, 2022	1,247	\$ 1	\$ 5,550	\$ 2	\$ 15,687	\$ (31)	\$ 21,209	
Net income (loss)	—	—	—	—	2,055	(32)	2,024	
Other comprehensive income, net	—	—	—	9	—	—	9	
Issuances under employee stock purchase plan	1	—	67	—	—	—	67	
Issuances under equity incentive plans	7	—	50	—	—	—	50	
Stock-based compensation	—	—	363	—	—	—	363	
Repurchases of common stock under repurchase programs (\$81.56 average price per share)	(7)	—	(24)	—	(526)	—	(550)	
Repurchases of common stock for employee tax withholding under equity incentive plans and other	(2)	—	—	—	(168)	—	(168)	
Dividends declared (\$1.50 per share)	—	—	—	—	(1,911)	—	(1,911)	
Balance as of June 30, 2023	1,247	\$ 1	\$ 6,008	\$ 10	\$ 15,138	\$ (64)	\$ 21,094	

See accompanying notes.

Three Months Ended June 30, 2022

(in millions, except per share amounts)	Gilead Stockholders' Equity						
	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Retained Earnings	Noncontrolling Interest	Total Stockholders' Equity
	Shares	Amount					
Balance as of March 31, 2022	1,255	\$ 1	\$ 4,867	\$ 73	\$ 14,986	\$ (12)	\$ 19,915
Net income (loss)	—	—	—	—	1,144	(9)	1,135
Other comprehensive income, net	—	—	—	14	—	—	14
Issuances under equity incentive plans	—	—	3	—	—	—	3
Stock-based compensation	—	—	164	—	—	—	164
Repurchases of common stock under repurchase programs (\$61.83 average price per share)	(1)	—	(3)	—	(67)	—	(70)
Repurchases of common stock for employee tax withholding under equity incentive plans	—	—	—	—	(14)	—	(14)
Dividends declared (\$0.73 per share)	—	—	—	—	(932)	—	(932)
Balance as of June 30, 2022	1,254	\$ 1	\$ 5,031	\$ 87	\$ 15,117	\$ (21)	\$ 20,215

Six Months Ended June 30, 2022

(in millions, except per share amounts)	Gilead Stockholders' Equity						
	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Retained Earnings	Noncontrolling Interest	Total Stockholders' Equity
	Shares	Amount					
Balance as of December 31, 2021	1,254	\$ 1	\$ 4,661	\$ 83	\$ 16,324	\$ (5)	\$ 21,064
Net income (loss)	—	—	—	—	1,163	(16)	1,147
Other comprehensive income, net	—	—	—	4	—	—	4
Issuances under employee stock purchase plan	1	—	73	—	—	—	73
Issuances under equity incentive plans	7	—	24	—	—	—	24
Stock-based compensation	—	—	295	—	—	—	295
Repurchases of common stock under repurchase programs (\$63.44 average price per share)	(6)	—	(22)	—	(402)	—	(424)
Repurchases of common stock for employee tax withholding under equity incentive plans	(2)	—	—	—	(104)	—	(104)
Dividends declared (\$1.46 per share)	—	—	—	—	(1,864)	—	(1,864)
Balance as of June 30, 2022	1,254	\$ 1	\$ 5,031	\$ 87	\$ 15,117	\$ (21)	\$ 20,215

See accompanying notes.

GILEAD SCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited)

(in millions)	Six Months Ended June 30,	
	2023	2022
Operating Activities:		
Net income	\$ 2,024	\$ 1,147
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation expense	177	160
Amortization expense	1,144	890
Stock-based compensation expense	363	295
Acquired in-process research and development expenses	717	338
In-process research and development impairment	—	2,700
Deferred income taxes	(524)	(944)
Net loss from equity securities	187	399
Other	205	420
Changes in operating assets and liabilities:		
Accounts receivable, net	549	247
Inventories	(453)	61
Prepaid expenses and other	66	(81)
Accounts payable	(275)	(104)
Income tax assets and liabilities, net	(189)	(591)
Accrued and other liabilities	91	(1,295)
Net cash provided by operating activities	4,082	3,642
Investing Activities:		
Purchases of marketable debt securities	(1,105)	(1,090)
Proceeds from sales of marketable debt securities	317	323
Proceeds from maturities of marketable debt securities	719	955
Acquisitions, including in-process research and development, net of cash acquired	(794)	(1,131)
Purchases of equity securities	(192)	(44)
Capital expenditures	(248)	(390)
Other	(6)	(1)
Net cash used in investing activities	(1,309)	(1,378)
Financing Activities:		
Proceeds from issuances of common stock	123	97
Repurchases of common stock under repurchase programs	(550)	(424)
Repayments of debt and other obligations	—	(500)
Payments of dividends	(1,913)	(1,865)
Other	(167)	(105)
Net cash used in financing activities	(2,507)	(2,797)
Effect of exchange rate changes on cash and cash equivalents	26	(66)
Net change in cash and cash equivalents	292	(599)
Cash and cash equivalents at beginning of period	5,412	5,338
Cash and cash equivalents at end of period	\$ 5,704	\$ 4,739

See accompanying notes.

GILEAD SCIENCES, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The accompanying Condensed Consolidated Financial Statements and related Notes to Condensed Consolidated Financial Statements of Gilead Sciences, Inc. (“Gilead,” “we,” “our” or “us”) should be read in conjunction with the audited Consolidated Financial Statements and the related notes thereto for the year ended December 31, 2022, included in our Annual Report on Form 10-K filed with U.S. Securities and Exchange Commission. There have been no material changes to our organization or summary of significant accounting policies as disclosed in that filing. Beginning in the first quarter of 2023, we reclassified changes in income taxes prepaid and receivable from Prepaid expenses and other to combine with changes in income taxes payable as Income tax assets and liabilities, net within Operating Activities on our Condensed Consolidated Statements of Cash Flows. We believe this presentation assists users of the financial statements to better understand cash flow movements. Prior periods have been revised to reflect this change, resulting in a reclassification of \$51 million from Prepaid expenses and other for the six months ended June 30, 2022.

These interim financial statements have been prepared in accordance with U.S. generally accepted accounting principles for interim financial information and include all adjustments consisting of normal recurring adjustments that the management of Gilead believes are necessary for a fair presentation of the periods presented and are not necessarily indicative of results expected for the full fiscal year or for any subsequent interim period. Certain amounts and percentages in these Condensed Consolidated Financial Statements and accompanying notes may not sum or recalculate due to rounding.

2. REVENUES

Disaggregation of Revenues

The following table summarizes our Total revenues:

(in millions)	Three Months Ended June 30, 2023				Three Months Ended June 30, 2022			
	U.S.	Europe	Other International	Total	U.S.	Europe	Other International	Total
Product sales:								
HIV								
Biktarvy	\$ 2,439	\$ 302	\$ 237	\$ 2,979	\$ 2,095	\$ 268	\$ 193	\$ 2,556
Complera/Eviplera	13	16	3	32	20	31	3	54
Descovy	460	25	31	516	397	32	32	460
Genvoya	455	56	29	540	482	72	29	582
Odefsey	267	74	11	351	255	97	12	364
Stribild	19	5	2	26	24	8	2	33
Truvada	32	3	7	42	24	5	5	34
Revenue share - Symtuza ⁽¹⁾	84	33	3	120	80	42	4	126
Other HIV ⁽²⁾	10	7	3	20	5	9	4	18
Total HIV	3,778	521	326	4,626	3,383	562	282	4,228
Oncology								
Cell Therapy								
Tecartus	56	29	4	88	53	20	—	73
Yescarta	217	133	30	380	193	85	17	295
Total Cell Therapy	272	162	34	469	246	105	17	368
Trodehvy	189	53	17	260	120	35	3	159
Total Oncology	462	215	51	728	366	141	21	527
Liver Disease								
Chronic hepatitis C virus ("HCV")								
Ledipasvir/Sofosbuvir ⁽³⁾	8	2	5	15	6	4	13	23
Sofosbuvir/Velpatasvir ⁽⁴⁾	223	84	90	397	227	75	74	376
Other HCV ⁽⁵⁾	28	9	3	40	30	16	3	49
Total HCV	259	95	98	452	263	94	91	448
Chronic hepatitis B virus ("HBV") / hepatitis delta virus ("HDV")								
Vemlidy	96	10	113	219	97	9	89	195
Viread	1	6	14	21	3	6	15	24
Other HBV/HDV ⁽⁶⁾	—	20	—	20	—	15	—	16
Total HBV/HDV	97	35	127	259	100	30	104	234
Total Liver Disease	356	131	225	711	363	124	195	682
Veklury	97	52	107	256	41	126	278	445
Other								
AmBisome	20	69	61	151	15	63	54	132
Letairis	39	—	—	39	49	—	—	49
Other ⁽⁷⁾	26	10	17	53	37	26	13	76
Total Other	85	80	78	243	101	88	67	256
Total product sales	4,777	999	788	6,564	4,254	1,042	842	6,138
Royalty, contract and other revenues	6	28	1	35	85	34	2	122
Total revenues	\$ 4,784	\$ 1,027	\$ 789	\$ 6,599	\$ 4,339	\$ 1,076	\$ 844	\$ 6,260

(in millions)	Six Months Ended June 30, 2023				Six Months Ended June 30, 2022			
	U.S.	Europe	Other International	Total	U.S.	Europe	Other International	Total
Product sales:								
HIV								
Biktarvy	\$ 4,600	\$ 606	\$ 449	\$ 5,656	\$ 3,801	\$ 529	\$ 376	\$ 4,707
Complera/Eviplera	27	37	6	70	37	55	7	99
Descovy	855	50	60	965	708	64	63	834
Genvoya	872	111	58	1,041	939	149	76	1,164
Odefsey	497	149	22	668	487	193	23	703
Stribild	39	11	4	55	46	16	5	66
Truvada	55	7	12	74	52	9	11	72
Revenue share - Symtuza ⁽¹⁾	182	70	7	259	166	86	6	258
Other HIV ⁽²⁾	15	8	6	29	10	13	9	33
Total HIV	7,142	1,049	624	8,816	6,245	1,112	577	7,935
Oncology								
Cell Therapy								
Tecartus	114	56	6	177	100	35	1	136
Yescarta	427	254	58	739	318	162	26	506
Total Cell Therapy	542	310	65	916	418	197	27	642
Trodelvy	351	107	23	482	240	61	5	305
Total Oncology	893	417	88	1,398	658	258	32	947
Liver Disease								
HCV								
Ledipasvir/Sofosbuvir ⁽³⁾	12	9	10	30	19	8	31	58
Sofosbuvir/Velpatasvir ⁽⁴⁾	427	174	181	782	389	157	159	706
Other HCV ⁽⁵⁾	51	27	6	85	54	24	5	83
Total HCV	491	209	197	897	462	189	196	847
HBV/HDV								
Vemlidy	183	19	216	418	177	18	199	394
Viread	1	12	28	40	3	12	32	47
Other HBV/HDV ⁽⁶⁾	—	31	—	31	—	28	—	28
Total HBV/HDV	183	62	244	489	180	57	232	470
Total Liver Disease	674	271	441	1,386	642	247	427	1,317
Veklury	349	163	317	829	843	430	708	1,980
Other								
AmBisome	27	129	111	267	40	129	107	275
Letairis	70	—	—	70	92	—	—	92
Other ⁽⁷⁾	56	22	26	105	63	41	22	125
Total Other	153	152	137	442	195	169	129	493
Total product sales	9,211	2,052	1,607	12,870	8,582	2,216	1,873	12,672
Royalty, contract and other revenues	25	54	3	81	112	61	5	178
Total revenues	\$ 9,236	\$ 2,106	\$ 1,610	\$ 12,951	\$ 8,694	\$ 2,277	\$ 1,878	\$ 12,850

⁽¹⁾ Represents our revenue from cobicistat ("C"), emtricitabine ("FTC") and tenofovir alafenamide ("TAF") in Symtuza (darunavir/CFTC/TAF), a fixed dose combination product commercialized by Janssen Sciences Ireland Unlimited Company ("Janssen").

⁽²⁾ Includes Atripla, Emtriva, Sunlenca and Tybost.

⁽³⁾ Amounts consist of sales of Harvoni and the authorized generic version of Harvoni sold by our separate subsidiary, Asegua Therapeutics LLC.

⁽⁴⁾ Amounts consist of sales of Epclusa and the authorized generic version of Epclusa sold by our separate subsidiary, Asegua Therapeutics LLC.

⁽⁵⁾ Includes Vosevi and Sovaldi.

⁽⁶⁾ Includes Hepcludex and Hepsera.

⁽⁷⁾ Includes Cayston, Jyseleca, Ranexa and Zydelig.

Revenues from Major Customers

The following table summarizes revenues from each of our customers who individually accounted for 10% or more of our Total revenues:

(as a percentage of total revenues)	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
AmerisourceBergen Corporation	19 %	17 %	18 %	18 %
Cardinal Health, Inc.	27 %	26 %	27 %	24 %
McKesson Corporation	20 %	20 %	20 %	20 %

Revenues Recognized from Performance Obligations Satisfied in Prior Periods

The following table summarizes revenues recognized from performance obligations satisfied in prior periods:

(in millions)	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenue share with Janssen and royalties for licenses of intellectual property	\$ 158	\$ 197	\$ 350	\$ 381
Changes in estimates	\$ 77	\$ 16	\$ 237	\$ 246

Contract Balances

The following table summarizes our contract balances:

(in millions)	June 30, 2023	December 31, 2022
Contract assets ⁽¹⁾	\$ 130	\$ 171
Contract liabilities ⁽²⁾	\$ 103	\$ 102

⁽¹⁾ Consists of unbilled amounts primarily from arrangements where the licensing of intellectual property is the only or predominant performance obligation.

⁽²⁾ Generally results from receipt of advance payment before our performance under the contract.

3. FAIR VALUE MEASUREMENTS

The following table summarizes the types of assets and liabilities measured at fair value on a recurring basis by level within the fair value hierarchy:

(in millions)	June 30, 2023				December 31, 2022			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Assets:								
Available-for-sale debt securities:								
U.S. treasury securities	\$ 375	\$ —	\$ —	\$ 375	\$ 410	\$ —	\$ —	\$ 410
U.S. government agencies securities	—	161	—	161	—	35	—	35
Non-U.S. government securities	—	15	—	15	—	34	—	34
Certificates of deposit	—	104	—	104	—	54	—	54
Corporate debt securities	—	1,338	—	1,338	—	1,427	—	1,427
Residential mortgage and asset-backed securities	—	346	—	346	—	333	—	333
Equity securities:								
Money market funds	4,253	—	—	4,253	3,831	—	—	3,831
Equity investment in Galapagos NV (“Galapagos”)	682	—	—	682	736	—	—	736
Equity investment in Arcus Biosciences, Inc. (“Arcus”)	301	—	—	301	286	—	—	286
Other publicly traded equity securities	226	—	—	226	175	—	—	175
Deferred compensation plan	268	—	—	268	220	—	—	220
Foreign currency derivative contracts	—	25	—	25	—	60	—	60
Total	\$ 6,105	\$ 1,991	\$ —	\$ 8,096	\$ 5,658	\$ 1,943	\$ —	\$ 7,600
Liabilities:								
Liability for MYR GmbH (“MYR”) contingent consideration	\$ —	\$ —	\$ 288	\$ 288	\$ —	\$ —	\$ 275	\$ 275
Deferred compensation plan	267	—	—	267	220	—	—	220
Foreign currency derivative contracts	—	36	—	36	—	42	—	42
Total	\$ 267	\$ 36	\$ 288	\$ 592	\$ 220	\$ 42	\$ 275	\$ 538

Level 2 Inputs

Available-for-Sale Debt Securities

For our available-for-sale debt securities, we estimate the fair values by reviewing trading activity and pricing as of the measurement date, and by taking into consideration valuations obtained from third-party pricing services. The pricing services utilize industry standard valuation models, including both income-based and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate the fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities, issuer credit spreads, benchmark securities, prepayment/default projections based on historical data and other observable inputs.

Foreign Currency Derivative Contracts

Our foreign currency derivative contracts have maturities of 18 months or less and all are with counterparties that have a minimum credit rating of A- or equivalent by S&P Global Ratings, Moody’s Investors Service, Inc. or Fitch Ratings, Inc. We estimate the fair values of these contracts by taking into consideration the valuations obtained from a third-party valuation service that utilizes an income-based industry standard valuation model for which all significant inputs are observable, either directly or indirectly. These inputs include foreign currency exchange rates, Secured Overnight Financing Rate and swap rates. These inputs, where applicable, are observable at commonly quoted intervals.

Senior Unsecured Notes

The total estimated fair value of our senior unsecured notes, determined using Level 2 inputs based on their quoted market values, was approximately \$22.3 billion and \$21.9 billion as of June 30, 2023 and December 31, 2022, respectively, and the carrying value was \$24.1 billion as of June 30, 2023 and December 31, 2022.

Level 3 Inputs

Contingent Consideration Liability

In connection with our first quarter 2021 acquisition of MYR, we are subject to a potential contingent consideration payment of up to €300 million, subject to customary adjustments, which is revalued each reporting period using probability-weighted scenarios for U.S. Food and Drug Administration (“FDA”) approval of Hepcludex until the related contingency is resolved.

The following table summarizes the change in fair value of our contingent consideration liability:

(in millions)	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Beginning balance	\$ 277	\$ 322	\$ 275	\$ 317
Changes in valuation assumptions ⁽¹⁾	8	—	5	11
Effect of foreign exchange remeasurement ⁽²⁾	2	(16)	7	(22)
Ending balance	<u>\$ 288</u>	<u>\$ 306</u>	<u>\$ 288</u>	<u>\$ 306</u>

⁽¹⁾ Included in Research and development expenses on our Condensed Consolidated Statements of Income. The change primarily related to updated probability rate estimates.

⁽²⁾ Included in Other income (expense), net on our Condensed Consolidated Statements of Income.

Liability Related to Future Royalties

We recorded a liability related to future royalties as part of our fourth quarter 2020 acquisition of Immunomedics, Inc. (“Immunomedics”), which is subsequently amortized using the effective interest method over the remaining estimated life. The fair value and the carrying value of the liability related to future royalties was \$1.1 billion as of June 30, 2023 and December 31, 2022.

Nonrecurring Fair Value Measurements

During the six months ended June 30, 2022, we recorded a partial impairment charge of \$2.7 billion related to certain acquired in-process research and development (“IPR&D”) assets. See Note 7. Intangible Assets for additional information. There were no indicators of impairment to IPR&D assets noted during the six months ended June 30, 2023.

Fair Value Level Transfers

There were no transfers between Level 1, Level 2 and Level 3 in the periods presented.

4. AVAILABLE-FOR-SALE DEBT SECURITIES AND EQUITY SECURITIES

Available-for-Sale Debt Securities

The following table summarizes our available-for-sale debt securities:

(in millions)	June 30, 2023				December 31, 2022			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. treasury securities	\$ 378	\$ —	\$ (3)	\$ 375	\$ 415	\$ —	\$ (5)	\$ 410
U.S. government agencies securities	162	—	(1)	161	36	—	—	35
Non-U.S. government securities	16	—	—	15	34	—	—	34
Certificates of deposit	104	—	—	104	54	—	—	54
Corporate debt securities	1,358	—	(20)	1,338	1,452	—	(26)	1,427
Residential mortgage and asset-backed securities	348	—	(2)	346	335	—	(3)	333
Total	\$ 2,367	\$ —	\$ (26)	\$ 2,341	\$ 2,325	\$ 1	\$ (34)	\$ 2,293

The following table summarizes information related to available-for-sale debt securities that have been in a continuous unrealized loss position, classified by length of time:

(in millions)	June 30, 2023					
	Less Than 12 Months		12 Months or Longer		Total	
	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value
U.S. treasury securities	\$ (2)	\$ 299	\$ (1)	\$ 46	\$ (3)	\$ 345
U.S. government agencies securities	(1)	149	—	—	(1)	149
Non-U.S. government securities	—	11	—	5	—	15
Corporate debt securities	(6)	522	(14)	647	(20)	1,168
Residential mortgage and asset-backed securities	(1)	266	—	42	(2)	308
Total	\$ (10)	\$ 1,246	\$ (16)	\$ 739	\$ (26)	\$ 1,985

(in millions)	December 31, 2022					
	Less Than 12 Months		12 Months or Longer		Total	
	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value
U.S. treasury securities	\$ (2)	\$ 174	\$ (3)	\$ 206	\$ (5)	\$ 379
U.S. government agencies securities	—	21	—	—	—	21
Non-U.S. government securities	—	31	—	3	—	34
Corporate debt securities	(17)	774	(8)	439	(26)	1,213
Residential mortgage and asset-backed securities	(2)	205	(1)	56	(3)	261
Total	\$ (22)	\$ 1,204	\$ (12)	\$ 705	\$ (34)	\$ 1,908

No allowance for credit losses was recognized for investments with unrealized losses as of June 30, 2023 as the unrealized losses were primarily driven by broader change in interest rates with no adverse conditions identified that would prevent the issuer from making scheduled principal and interest payments. We do not currently intend to sell, and it is not more likely than not that we will be required to sell, such investments before recovery of their amortized cost bases.

The following table summarizes the classification of our available-for-sale debt securities in our Condensed Consolidated Balance Sheets:

(in millions)	June 30, 2023	December 31, 2022
Cash and cash equivalents	\$ 44	\$ 75
Short-term marketable debt securities	963	973
Long-term marketable debt securities	1,334	1,245
Total	\$ 2,341	\$ 2,293

The following table summarizes our available-for-sale debt securities by contractual maturity:

(in millions)	June 30, 2023	
	Amortized Cost	Fair Value
Within one year	\$ 1,014	\$ 1,007
After one year through five years	1,332	1,313
After five years through ten years	17	16
After ten years	4	4
Total	<u>\$ 2,367</u>	<u>\$ 2,341</u>

Equity Securities

Equity Securities Measured at Fair Value

The following table summarizes the classification of our equity securities measured at fair value on a recurring basis, on our Condensed Consolidated Balance Sheets:

(in millions)	June 30, 2023	December 31, 2022
Cash and cash equivalents	\$ 4,253	\$ 3,831
Prepaid and other current assets ⁽¹⁾	431	473
Other long-term assets ⁽¹⁾	1,046	943
Total	<u>\$ 5,730</u>	<u>\$ 5,248</u>

⁽¹⁾ Prepaid and other current assets and Other long-term assets include our equity method investments in Arcus and Galapagos, respectively, for which we elected and applied the fair value option as we believe it best reflects the underlying economics of these investments. Our investment in Galapagos is classified in Other long-term assets due to certain lock-up provisions in our amended subscription agreement with them, which extend to August 2024.

Other Equity Securities

Equity method investments and other equity investments without readily determinable fair values were \$366 million and \$423 million as of June 30, 2023 and December 31, 2022, respectively, and were excluded from the table above. These amounts were included in Other long-term assets on our Condensed Consolidated Balance Sheets.

Unrealized Gains and Losses

We recognized \$69 million net unrealized gains and \$187 million net unrealized losses on equity securities for the three and six months ended June 30, 2023, respectively, and \$303 million and \$399 million net unrealized losses on equity securities for the three and six months ended June 30, 2022, respectively, which were included in Other income (expense), net on our Condensed Consolidated Statements of Income.

Related Party Transaction

During the three months ended June 30, 2022, Gilead donated certain equity securities at fair value to the Gilead Foundation, a California nonprofit public benefit corporation (the "Foundation"). The Foundation is a related party as certain of our officers also serve as directors of the Foundation. The donation expense of \$85 million was recorded within Selling, general and administrative expenses on our Condensed Consolidated Statements of Income during the three months ended June 30, 2022.

5. DERIVATIVE FINANCIAL INSTRUMENTS

Our operations in foreign countries expose us to market risk associated with foreign currency exchange rate fluctuations between the U.S. dollar and various foreign currencies, primarily the Euro. To manage this risk, we hedge a portion of our foreign currency exposures related to outstanding monetary assets and liabilities as well as forecasted product sales using foreign currency exchange forward contracts. In general, the market risk related to these contracts is offset by corresponding gains and losses on the hedged transactions. The credit risk associated with these contracts is driven by changes in interest and currency exchange rates and, as a result, varies over time. By working only with major banks and closely monitoring current market conditions, we seek to limit the risk that counterparties to these contracts may be unable to perform. We also seek to limit our risk of loss by entering into contracts that permit net settlement at maturity. Therefore, our overall risk of loss in the event of a counterparty default is limited to the amount of any unrealized gains on outstanding contracts (i.e., those contracts that have a positive fair value) at the date of default. We do not enter into derivative contracts for trading purposes.

The derivative instruments we use to hedge our exposures for certain monetary assets and liabilities that are denominated in a non-functional currency are not designated as hedges. The derivative instruments we use to hedge our exposures for forecasted product sales are designated as cash flow hedges and have maturities of 18 months or less.

We held foreign currency exchange contracts with outstanding notional amounts of \$2.4 billion as of June 30, 2023 and \$3.0 billion as of December 31, 2022.

While all our derivative contracts allow us the right to offset assets and liabilities, we have presented amounts in our Condensed Consolidated Balance Sheets on a gross basis. The following table summarizes the classification and fair values of derivative instruments, including the potential effect of offsetting:

(in millions)	June 30, 2023			
	Derivative Assets		Derivative Liabilities	
	Classification	Fair Value	Classification	Fair Value
Derivatives designated as hedges:				
Foreign currency exchange contracts	Prepaid and other current assets	\$ 23	Other current liabilities	\$ 34
Foreign currency exchange contracts	Other long-term assets	2	Other long-term obligations	2
Total derivatives designated as hedges		24		36
Derivatives not designated as hedges:				
Foreign currency exchange contracts	Prepaid and other current assets	1	Other current liabilities	—
Total derivatives not designated as hedges		1		—
Total derivatives presented gross on the Condensed Consolidated Balance Sheets		\$ 25		\$ 36
Gross amounts not offset on the Condensed Consolidated Balance Sheets:				
Derivative financial instruments		(19)		(19)
Cash collateral received / pledged		—		—
Net amount (legal offset)		\$ 6		\$ 17

(in millions)	December 31, 2022			
	Derivative Assets		Derivative Liabilities	
	Classification	Fair Value	Classification	Fair Value
Derivatives designated as hedges:				
Foreign currency exchange contracts	Prepaid and other current assets	\$ 59	Other current liabilities	\$ 26
Foreign currency exchange contracts	Other long-term assets	1	Other long-term obligations	9
Total derivatives designated as hedges		59		35
Derivatives not designated as hedges:				
Foreign currency exchange contracts	Prepaid and other current assets	1	Other current liabilities	7
Total derivatives not designated as hedges		1		7
Total derivatives presented gross on the Condensed Consolidated Balance Sheets		\$ 60		\$ 42
Gross amounts not offset on the Condensed Consolidated Balance Sheets:				
Derivative financial instruments		(36)		(36)
Cash collateral received / pledged		—		—
Net amount (legal offset)		\$ 25		\$ 7

The following table summarizes the effect of our derivative contracts on our Condensed Consolidated Financial Statements:

(in millions)	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Derivatives designated as hedges:				
Net gain (loss) recognized in Accumulated other comprehensive income	\$ 5	\$ 102	\$ (1)	\$ 130
Net gain reclassified from Accumulated other comprehensive income into Product sales	\$ 10	\$ 45	\$ 34	\$ 67
Derivatives not designated as hedges:				
Net gain recognized in Other income (expense), net	\$ 53	\$ 45	\$ 50	\$ 63

The majority of gains and losses related to the hedged forecasted transactions reported in Accumulated other comprehensive income as of June 30, 2023 are expected to be reclassified to Product sales within 12 months. There were no discontinuances of cash flow hedges for the three and six months ended June 30, 2023 and 2022.

The cash flow effects of our derivative contracts for the six months ended June 30, 2023 and 2022 were included within Net cash provided by operating activities on our Condensed Consolidated Statements of Cash Flows.

6. ACQUISITIONS, COLLABORATIONS AND OTHER ARRANGEMENTS

We enter into acquisitions, licensing and strategic collaborations and other similar arrangements with third parties for the development and commercialization of certain products and product candidates. The collaborations and other arrangements may involve two or more parties who are active participants in the operating activities of the collaboration and are exposed to significant risks and rewards depending on the commercial success of the activities. These arrangements may include non-refundable upfront payments, expense reimbursements or payments by us for options to acquire certain rights, contingent obligations by us for potential development and regulatory milestone payments and/or sales-based milestone payments, royalty payments, revenue or profit-sharing arrangements, cost-sharing arrangements and equity investments.

Acquisitions

XinThera

In May 2023, we closed an agreement to acquire XinThera, Inc. (“XinThera”), a privately held biotechnology company focused on small molecule drugs to treat cancer and immunologic diseases, for approximately \$200 million in cash consideration, net of cash acquired. As a result, XinThera became our wholly-owned subsidiary.

We accounted for the transaction as an asset acquisition and recorded a \$170 million charge to Acquired in-process research and development expenses on our Condensed Consolidated Statements of Income during the three months ended June 30, 2023. The remaining purchase price relates to various other assets acquired and liabilities assumed. Under the agreement, the former shareholders of XinThera are eligible to receive performance-based development and regulatory milestone payments of up to approximately \$760 million.

Tmunity

In February 2023, we closed an agreement to acquire Tmunity Therapeutics, Inc. (“Tmunity”), a clinical-stage, private biotechnology company focused on next-generation CAR T-therapies and technologies. Under the terms of the agreement, we acquired all outstanding shares of Tmunity other than those already owned by Gilead for approximately \$300 million in cash consideration. As a result, Tmunity became our wholly-owned subsidiary.

We accounted for the transaction as an asset acquisition and recorded a \$244 million charge to Acquired in-process research and development expenses on our Condensed Consolidated Statements of Income during the three months ended March 31, 2023. The remaining purchase price relates to various other assets acquired and liabilities assumed, consisting primarily of deferred tax assets. Under the agreement, the former shareholders of Tmunity and the University of Pennsylvania are eligible to receive a mix of up to approximately \$1.0 billion in potential future payments upon achievement of certain development, regulatory and sales-based milestones, as well as royalty payments on sales.

Collaborations and Other Arrangements

Arcellx

In January 2023, we closed an agreement to enter into a global strategic collaboration with Arcellx, Inc. (“Arcellx”) to co-develop and co-commercialize Arcellx’s lead late-stage product candidate, CART-ddBCMA, for the treatment of patients with relapsed or refractory multiple myeloma, and potential future next-generation autologous and non-autologous products. In conjunction with the collaboration agreement, we recorded a \$212 million charge to Acquired in-process research and development expenses on our Condensed Consolidated Statements of Income during the three months ended March 31, 2023, primarily related to an upfront payment, as well as a \$115 million equity investment, which is subject to lock-up provisions until July 2024, in Other long-term assets on our Condensed Consolidated Balance Sheets. The companies will share development, clinical trial, and commercialization costs for CART-ddBCMA and will jointly commercialize the product and split U.S. profits 50/50. Outside the U.S., we will commercialize the product and Arcellx will receive royalties on sales. Arcellx is eligible to receive performance-based development and regulatory milestone payments of up to \$835 million related to CART-ddBCMA, a potential future next-generation autologous product and a potential future non-autologous product, with further commercial milestone payments, profit split payments on co-promote products and royalties on at least a portion of worldwide net sales, depending on whether Arcellx opts-in to co-promote on the future products. If additional future products are developed, Arcellx would be eligible to receive additional milestone payments, profit split payments on co-promote products and royalties on at least a portion of worldwide net sales, depending on whether Arcellx opts-in to co-promote these additional future products as well.

Pionyr

In June 2020, we entered into a transaction with Pionyr Immunotherapeutics (“Pionyr”), a privately held company pursuing novel biology in the field of immunology, which included entry into two separate agreements, one related to the initial acquisition of a 49.9% equity interest in Pionyr and the other providing us with the exclusive option, subject to certain terms and conditions, to acquire the remaining outstanding capital stock of Pionyr (“Pionyr Merger and Option Agreements”). The exclusive option had an estimated fair value of \$70 million based on a probability-weighted option pricing model using unobservable inputs, which are considered Level 3 under the fair value measurement and disclosure guidance. In March 2023, we waived our exclusive option to acquire Pionyr and certain other rights under the Pionyr Merger and Option Agreements and recorded a \$70 million charge to Other income (expense), net on our Condensed Consolidated Statements of Income during the three months ended March 31, 2023. We will retain our equity interest in Pionyr as well as the right, under certain conditions, to review new data as it emerges.

7. INTANGIBLE ASSETS

The following table summarizes our Intangible assets, net:

(in millions)	June 30, 2023				December 31, 2022			
	Gross Carrying Amount	Accumulated Amortization	Foreign Currency Translation Adjustment	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Foreign Currency Translation Adjustment	Net Carrying Amount
Finite-lived assets:								
Intangible asset – sofosbuvir	\$ 10,720	\$ (6,700)	\$ —	\$ 4,020	\$ 10,720	\$ (6,350)	\$ —	\$ 4,370
Intangible asset – axicabtagene ciloleucel	7,110	(2,111)	—	4,999	7,110	(1,908)	—	5,202
Intangible asset – Trodelvy ⁽¹⁾	11,730	(1,462)	—	10,268	5,630	(973)	—	4,657
Intangible asset – Hepcludex	845	(201)	—	644	845	(158)	—	687
Other	1,489	(792)	1	698	1,489	(733)	1	758
Total finite-lived assets	31,894	(11,265)	1	20,630	25,794	(10,121)	1	15,674
Indefinite-lived assets – IPR&D ⁽¹⁾	7,120	—	—	7,120	13,220	—	—	13,220
Total intangible assets	<u>\$ 39,014</u>	<u>\$ (11,265)</u>	<u>\$ 1</u>	<u>\$ 27,750</u>	<u>\$ 39,014</u>	<u>\$ (10,121)</u>	<u>\$ 1</u>	<u>\$ 28,894</u>

⁽¹⁾ In February 2023, FDA granted approval of Trodelvy for use in adult patients with unresectable locally advanced or metastatic HR+/HER2- breast cancer who have received endocrine-based therapy and at least two additional systemic therapies in the metastatic setting. Accordingly, the related IPR&D intangible asset of \$ 6.1 billion was reclassified to finite-lived assets in the first quarter of 2023.

Amortization Expense

Aggregate amortization expense related to finite-lived intangible assets was \$598 million and \$1.1 billion for the three and six months ended June 30, 2023, respectively, and \$445 million and \$890 million for the three and six months ended June 30, 2022, respectively, and is primarily included in Cost of goods sold on our Condensed Consolidated Statements of Income.

The following table summarizes the estimated future amortization expense associated with our finite-lived intangible assets as of June 30, 2023:

(in millions)	Amount
2023 (remaining six months)	\$ 1,196
2024	2,392
2025	2,386
2026	2,378
2027	2,378
Thereafter	9,900
Total	<u>\$ 20,630</u>

Impairment Assessments

No indicators of impairment were noted for the three and six months ended June 30, 2023 and 2022, except as described under “2022 IPR&D Impairment” below.

2022 IPR&D Impairment

In connection with our acquisition of Immunomedics in 2020, we allocated a portion of the purchase price to acquired IPR&D intangible assets. Approximately \$8.8 billion was assigned to IPR&D intangible assets related to Trodelvy for treatment of patients with hormone receptor-positive, human epidermal growth factor receptor 2-negative ("HR+/HER2-") breast cancer. In March 2022, we received data from the Phase 3 TROPiCS-02 study evaluating Trodelvy in patients with HR+/HER2- metastatic breast cancer who have received prior endocrine therapy, cyclin-dependent kinase 4/6 inhibitors and two to four lines of chemotherapy ("third-line plus patients"). Based on our evaluation of the study results, and in connection with the preparation of the financial statements for the first quarter, we updated our estimate of the fair value of our HR+/HER2- IPR&D intangible asset to \$6.1 billion as of March 31, 2022. Our estimate of fair value used a probability-weighted income approach that discounts expected future cash flows to the present value, which requires the use of Level 3 fair value measurements and inputs, including estimated revenues, costs, and probability of technical and regulatory success. The expected cash flows included cash flows from HR+/HER2- metastatic breast cancer for third-line plus patients and patients in earlier lines of therapy which are the subject of separate clinical studies. Our revised discounted cash flows were lower primarily due to a delay in launch timing for third-line plus patients which caused a decrease in our market share assumptions based on the expected competitive environment. As of March 2022, there were no changes in our plans or assumptions related to our estimated cash flows for patients in the earlier lines of therapy. We used a discount rate of 6.75% which is based on the estimated weighted-average cost of capital for companies with profiles similar to ours and represents the rate that market participants would use to value the intangible assets. We determined the revised estimated fair value was below the carrying value of the asset and, as a result, we recognized a partial impairment charge of \$2.7 billion in In-process research and development impairment on our Condensed Consolidated Statements of Income during the three months ended March 31, 2022.

8. OTHER FINANCIAL INFORMATION

Accounts receivable, net

The following table summarizes our Accounts receivable, net:

(in millions)	June 30, 2023	December 31, 2022
Accounts receivable	\$ 5,049	\$ 5,464
Less: allowances for chargebacks	665	549
Less: allowances for cash discounts and other	96	83
Less: allowances for credit losses	59	55
Accounts receivable, net	<u>\$ 4,229</u>	<u>\$ 4,777</u>

The majority of our trade accounts receivable arises from product sales in the U.S. and Europe.

Inventories

The following table summarizes our Inventories:

(in millions)	June 30, 2023	December 31, 2022
Raw materials	\$ 1,231	\$ 1,177
Work in process	622	577
Finished goods	1,327	1,066
Total	<u>\$ 3,181</u>	<u>\$ 2,820</u>
Reported as:		
Inventories	\$ 1,633	\$ 1,507
Other long-term assets ⁽¹⁾	1,547	1,313
Total	<u>\$ 3,181</u>	<u>\$ 2,820</u>

⁽¹⁾ Amounts primarily consist of raw materials.

Other current liabilities

The following table summarizes the components of Other current liabilities:

(in millions)	June 30, 2023	December 31, 2022
Compensation and employee benefits	\$ 764	\$ 1,018
Income taxes payable	2,226	959
Allowance for sales returns	438	422
Other	2,383	2,182
Other current liabilities	<u>\$ 5,810</u>	<u>\$ 4,580</u>

Accumulated other comprehensive income

The following tables summarize the changes in Accumulated other comprehensive income by component, net of tax

(in millions)	Foreign Currency Translation	Unrealized Gains and Losses on Available-for-Sale Debt Securities, Net of Tax	Unrealized Gains and Losses on Cash Flow Hedges, Net of Tax	Total
Balance as of December 31, 2022	\$ 2	\$ (33)	\$ 33	\$ 2
Net unrealized gain (loss)	32	6	(1)	37
Reclassifications to net income	—	1	(29)	(28)
Net current period other comprehensive income (loss)	32	7	(30)	9
Balance as of June 30, 2023	<u>\$ 34</u>	<u>\$ (26)</u>	<u>\$ 3</u>	<u>\$ 10</u>

(in millions)	Foreign Currency Translation	Unrealized Gains and Losses on Available-for-Sale Debt Securities, Net of Tax	Unrealized Gains and Losses on Cash Flow Hedges, Net of Tax	Total
Balance as of December 31, 2021	\$ 13	\$ (4)	\$ 74	\$ 83
Net unrealized gain (loss)	(21)	(31)	114	62
Reclassifications to net income	—	1	(59)	(58)
Net current period other comprehensive income (loss)	(21)	(30)	55	4
Balance as of June 30, 2022	<u>\$ (8)</u>	<u>\$ (34)</u>	<u>\$ 129</u>	<u>\$ 87</u>

9. DEBT AND CREDIT FACILITIES

The following table summarizes the carrying amount of our borrowings under various financing arrangements:

(in millions)				Carrying Amount	
Type of Borrowing	Issue Date	Maturity Date	Interest Rate	June 30, 2023	December 31, 2022
Senior Unsecured	September 2016	September 2023	2.50%	\$ 750	\$ 749
Senior Unsecured	September 2020	September 2023	0.75%	1,499	1,498
Senior Unsecured	March 2014	April 2024	3.70%	1,749	1,748
Senior Unsecured	November 2014	February 2025	3.50%	1,749	1,748
Senior Unsecured	September 2015	March 2026	3.65%	2,743	2,742
Senior Unsecured	September 2016	March 2027	2.95%	1,248	1,247
Senior Unsecured	September 2020	October 2027	1.20%	747	747
Senior Unsecured	September 2020	October 2030	1.65%	994	993
Senior Unsecured	September 2015	September 2035	4.60%	993	993
Senior Unsecured	September 2016	September 2036	4.00%	743	742
Senior Unsecured	September 2020	October 2040	2.60%	988	988
Senior Unsecured	December 2011	December 2041	5.65%	996	996
Senior Unsecured	March 2014	April 2044	4.80%	1,737	1,736
Senior Unsecured	November 2014	February 2045	4.50%	1,734	1,733
Senior Unsecured	September 2015	March 2046	4.75%	2,222	2,221
Senior Unsecured	September 2016	March 2047	4.15%	1,728	1,728
Senior Unsecured	September 2020	October 2050	2.80%	1,478	1,477
Total senior unsecured notes				24,096	24,088
Liability related to future royalties				1,150	1,141
Total debt, net				25,246	25,229
Less: Current portion of long-term debt and other obligations, net				4,037	2,273
Total Long-term debt, net				\$ 21,209	\$ 22,957

Senior Unsecured Notes

We are required to comply with certain covenants under our note indentures governing our senior unsecured notes. As of June 30, 2023, we were not in violation of any covenants.

Revolving Credit Facility

As of June 30, 2023 and December 31, 2022, there were no amounts outstanding under our \$2.5 billion revolving credit facility maturing in June 2025, and we were in compliance with all covenants.

10. COMMITMENTS AND CONTINGENCIES

Legal Proceedings

We are a party to various legal actions. Certain significant matters are described below. We recognize accruals for such actions to the extent that we conclude that a loss is both probable and reasonably estimable. We accrue for the best estimate of a loss within a range; however, if no estimate in the range is better than any other, then we accrue the minimum amount in the range. If we determine that a material loss is reasonably possible and the loss or range of loss can be estimated, we disclose the possible loss. Unless otherwise noted, the outcome of these matters either is not expected to be material or is not possible to determine such that we cannot reasonably estimate the maximum potential exposure or the range of possible loss. As of June 30, 2023, we recorded an accrual of \$525 million in Other current liabilities on our Condensed Consolidated Balance Sheets for settlements with certain plaintiffs in the HIV antitrust litigation. We did not have any other material accruals for the matters described below as of June 30, 2023.

Litigation Related to Sofosbuvir

In 2012, we acquired Pharmasset, Inc. Through the acquisition, we acquired sofosbuvir, a nucleotide analog that acts to inhibit the replication of HCV. In 2013, we received approval from FDA for sofosbuvir, sold under the brand name Sovaldi. Sofosbuvir is also included in all of our marketed HCV products. We have received a number of litigation claims regarding sofosbuvir. While we have carefully considered these claims both prior to and following the acquisition and believe they are without merit, we cannot predict the ultimate outcome of such claims or range of loss.

We are aware of patents and patent applications owned by third parties that have been or may in the future be alleged by such parties to cover the use of our HCV products. If third parties obtain valid and enforceable patents, and successfully prove infringement of those patents by our HCV products, we could be required to pay significant monetary damages. We cannot predict the ultimate outcome of intellectual property claims related to our HCV products. We have spent, and will continue to spend, significant resources defending against these claims.

Litigation with the University of Minnesota

The University of Minnesota (the “University”) has obtained U.S. Patent No. 8,815,830 (the “’830 patent”), which purports to broadly cover nucleosides with antiviral and anticancer activity. In 2016, the University filed a lawsuit against us in the U.S. District Court for the District of Minnesota, alleging that the commercialization of sofosbuvir-containing products infringes the ’830 patent. We believe the ’830 patent is invalid and will not be infringed by the continued commercialization of sofosbuvir. In 2017, the court granted our motion to transfer the case to California. We have also filed petitions for inter partes review with the U.S. Patent and Trademark Office Patent Trial and Appeal Board (“PTAB”) alleging that all asserted claims are invalid for anticipation and obviousness. The PTAB instituted one of these petitions and a merits hearing was held in February 2021. In 2018, the U.S. District Court for the Northern District of California stayed the litigation until after the PTAB concluded the inter partes review that it had initiated. In May 2021, the PTAB issued a written decision finding the asserted claims of the University’s patent invalid. In July 2021, the University appealed this decision, and in March 2023, a three-judge panel of the Court of Appeals for the Federal Circuit affirmed the PTAB’s decision. The litigation in the District Court was dismissed in April 2023 after the University did not pursue any further appeals.

Litigation Relating to Pre-Exposure Prophylaxis

In August 2019, we filed petitions requesting inter partes review of U.S. Patent Nos. 9,044,509, 9,579,333, 9,937,191 and 10,335,423 (collectively, “HHS Patents”) by PTAB. The HHS Patents are assigned to the U.S. Department of Health and Human Services (“HHS”) and purport to claim a process of protecting a primate host from infection by an immunodeficiency retrovirus by administering a combination of FTC and tenofovir disoproxil fumarate (“TDF”) or TAF prior to exposure of the host to the immunodeficiency retrovirus, a process commonly known as pre-exposure prophylaxis (“PrEP”). In November 2019, the U.S. Department of Justice filed a lawsuit against us in the U.S. District Court of Delaware, alleging that the sale of Truvada and Descovy for use as PrEP infringes the HHS Patents. In February 2020, PTAB declined to institute our petitions for inter partes review of the HHS Patents. In April 2020, we filed a lawsuit against the U.S. federal government in the U.S. Court of Federal Claims (“CFC”), alleging breach of three material transfer agreements (“MTAs”) related to the research underlying the HHS Patents and two clinical trial agreements (“CTAs”) by the U.S. Centers for Disease Control and Prevention related to PrEP research. A trial for the bifurcated portion of the lawsuit in the CFC was held in June 2022, and in November 2022, the CFC determined that the government breached the MTAs. The CFC also made findings of fact relating to the CTAs but declined to issue a decision on breach of the CTAs at least until after trial in the District Court. In May 2023, the District Court held a trial regarding the government’s patent infringement claims, and the jury rendered a full defense verdict in favor of Gilead, finding that the asserted claims of the HHS Patents are invalid and not infringed. The government has filed post-trial motions, and we expect the District Court to issue a decision by September 2023. Although we cannot predict with certainty the ultimate outcome of each of these litigation matters, we believe that the U.S. federal government breached its contracts with Gilead, that Truvada and Descovy do not infringe the HHS Patents and that the HHS Patents are invalid over prior art descriptions of Truvada’s use for PrEP and post-exposure prophylaxis as well because physicians and patients were using the claimed methods years before HHS filed the applications for the patents. A separate trial at the CFC to determine the damages Gilead is owed based on the government’s breach has yet to be scheduled.

Litigation with Generic Manufacturers

As part of the approval process for some of our products, FDA granted us a New Chemical Entity (“NCE”) exclusivity period during which other manufacturers’ applications for approval of generic versions of our products will not be approved. Generic manufacturers may challenge the patents protecting products that have been granted NCE exclusivity one year prior to the end of the NCE exclusivity period. Generic manufacturers have sought and may continue to seek FDA approval for a similar or identical drug through an abbreviated new drug application (“ANDA”), the application form typically used by manufacturers seeking approval of a generic drug. The sale of generic versions of our products prior to their patent expiration would have a significant negative effect on our revenues and results of operations. To seek approval for a generic version of a product having NCE status, a generic company may submit its ANDA to FDA four years after the branded product’s approval.

In October 2021, we received a letter from Lupin Ltd. (“Lupin”) indicating that it has submitted an ANDA to FDA requesting permission to market and manufacture a generic version of Symtuza, a product commercialized by Janssen and for which Gilead shares in revenues. In November 2021, we, along with Janssen and Janssen Products, L.P., filed a patent infringement lawsuit against Lupin as co-plaintiffs in the U.S. District Court of Delaware. In September 2022, we received a letter from Apotex Inc. and Apotex Corp. (“Apotex”) stating that they have submitted an ANDA for a generic version of Symtuza. In October 2022, we, along with Janssen and Janssen Products, L.P., filed a patent infringement lawsuit against Apotex as co-plaintiffs in the U.S. District Court of Delaware. The cases against Lupin and Apotex have been consolidated into a single trial scheduled for May 2024. We separately filed an additional lawsuit against Apotex asserting infringement of two additional patents in the same court.

Starting in March 2022, we received letters from Lupin, Laurus Labs (“Laurus”) and Cipla Ltd. (“Cipla”), indicating that they have submitted ANDAs to FDA requesting permission to market and manufacture generic versions of Biktarvy. Lupin, Laurus, and Cipla have challenged the validity of three of the five patents listed in the Orange Book as associated with Biktarvy. We filed a lawsuit against Lupin, Laurus and Cipla in May 2022 in the U.S. District Court of Delaware, and intend to enforce and defend our intellectual property. Trial has been scheduled for December 2024.

In June 2023, we received a letter from Apotex indicating that it has submitted an ANDA to FDA requesting permission to market and manufacture a generic version of Genvoya. In July 2023, we filed a patent infringement lawsuit against Apotex in the U.S. District Court of Delaware, and intend to enforce and defend our intellectual property.

European Patent Claims

In 2015, several parties filed oppositions in the European Patent Office (“EPO”) requesting revocation of one of our granted European patents covering sofosbuvir that expires in 2028. In 2016, the EPO upheld the validity of certain claims of our sofosbuvir patent. We have appealed this decision, seeking to restore all of the original claims, and several of the original opposing parties have also appealed, requesting full revocation. The appeal hearing was held in November 2022, but a final decision regarding the validity of the claims has not yet been announced.

In 2017, several parties filed oppositions in the EPO requesting revocation of our granted European patent relating to sofosbuvir that expires in 2024. The EPO conducted an oral hearing for this opposition in 2018 and upheld the claims. The original opposing parties have appealed, requesting full revocation. The hearing for the appeal has been scheduled for September 2023.

In 2017, several parties filed oppositions in the EPO requesting revocation of our granted European patent relating to TAF hemifumarate that expires in 2032. In 2019, the EPO upheld the validity of the claims of our TAF hemifumarate patent. Three parties have appealed this decision. The appeal hearing was held in March 2023 and the EPO affirmed the validity of the TAF hemifumarate patent.

The appeal process for sofosbuvir opposition proceedings may take several years. While we are confident in the strength of our patents, we cannot predict the ultimate outcome of these oppositions. If we are unsuccessful in defending these oppositions, some or all of our patent claims may be narrowed or revoked and the patent protection for sofosbuvir in the EU could be substantially shortened or eliminated entirely. If our patents are revoked, and no other European patents are granted covering these compounds, our exclusivity may be based entirely on regulatory exclusivity granted by EMA. If we lose patent protection for sofosbuvir, our revenues and results of operations could be negatively impacted for the years including and succeeding the year in which such exclusivity is lost.

Antitrust and Consumer Protection

We, along with Bristol-Myers Squibb Company (“BMS”), Johnson & Johnson, Inc. (“Johnson & Johnson”), and Teva Pharmaceutical Industries Ltd. (“Teva”) have been named as defendants in class action lawsuits filed in 2019 and 2020 related to various drugs used to treat HIV, including drugs used in combination antiretroviral therapy. Plaintiffs allege that we (and the other defendants) engaged in various conduct to restrain competition in violation of federal and state antitrust laws and state consumer protection laws. The lawsuits, which have been consolidated, are pending in the U.S. District Court for the Northern District of California. The lawsuits seek to bring claims on behalf of direct purchasers consisting largely of wholesalers and indirect or end-payor purchasers, including health insurers and individual patients. Plaintiffs seek damages, permanent injunctive relief and other relief. In the second half of 2021 and first half of 2022, several plaintiffs consisting of retail pharmacies, individual health plans and United Healthcare, filed separate lawsuits effectively opting out of the class action cases, asserting claims that are substantively the same as the classes. These cases have been coordinated with the class actions. In March 2023, the District Court granted our motion to hold separate trials as to (i) the allegations against us and Teva seeking monetary damages relating to Truvada and Atripla (“Phase I”) and (ii) the allegations against us and, in part, Johnson & Johnson, seeking monetary damages and injunctive relief relating to Complera (“Phase II”). In May 2023, we settled claims with the direct purchaser class and the retailer opt-out plaintiffs for \$525 million, which we have agreed to pay in the second half of 2023. The settlement agreements are not an admission of liability or fault by us, and are subject to a number of other conditions including, with respect to the preliminary settlement agreement between us and the direct purchaser class, court approval. From May 2023 through June 2023, a jury trial was held on the remaining plaintiffs’ Phase I allegations. The jury returned a complete verdict in Gilead’s favor. Trial on the Phase II claims has not yet been scheduled. While we believe the Phase II claims are without merit, we cannot predict the ultimate outcome. If the plaintiffs are successful in their Phase II claims, we could be required to pay monetary damages or could be subject to permanent injunctive relief in favor of the plaintiffs.

In January 2022, we, along with BMS and Janssen Products, L.P., were named as defendants in a lawsuit filed in the Superior Court of the State of California, County of San Mateo, by Aetna, Inc. on behalf of itself and its affiliates and subsidiaries that effectively opts the Aetna plaintiffs out of the above class actions. The allegations are substantively the same as those in the class actions. The Aetna plaintiffs seek damages, permanent injunctive relief and other relief.

In September 2020, we, along with generic manufacturers Cipla and Cipla USA Inc. (together, “Cipla Defendants”), were named as defendants in a class action lawsuit filed in the U.S. District Court for the Northern District of California by Jacksonville Police Officers and Fire Fighters Health Insurance Trust (“Jacksonville Trust”) on behalf of end-payor purchasers. Jacksonville Trust claims that the 2014 settlement agreement between us and the Cipla Defendants, which settled a patent dispute relating to patents covering our Emtriva, Truvada and Atripla products and permitted generic entry prior to patent expiry, violates certain federal and state antitrust and consumer protection laws. The Plaintiff seeks damages, permanent injunctive relief and other relief.

In February 2021, we, along with BMS and Teva Pharmaceutical Industries Ltd., were named as defendants in a lawsuit filed in the First Judicial District Court for the State of New Mexico, County of Santa Fe by the New Mexico Attorney General. The New Mexico Attorney General alleges that we (and the other defendants) restrained competition in violation of New Mexico antitrust and consumer protection laws. The New Mexico Attorney General seeks damages, permanent injunctive relief and other relief.

While we believe these cases are without merit, we cannot predict the ultimate outcome. If plaintiffs are successful in their claims, we could be required to pay significant monetary damages or could be subject to permanent injunctive relief awarded in favor of plaintiffs.

Product Liability

We have been named as a defendant in one class action lawsuit and various product liability lawsuits related to Viread, Truvada, Atripla, Complera and Stribild. Plaintiffs allege that Viread, Truvada, Atripla, Complera and/or Stribild caused them to experience kidney, bone and/or tooth injuries. The lawsuits, which are pending in state or federal court in California, Delaware, and Missouri, involve more than 25,000 active plaintiffs. Plaintiffs in these cases seek damages and other relief on various grounds for alleged personal injury and economic loss. The first bellwether trial in California state court was scheduled to begin in October 2022, but is currently stayed while the California First District Court of Appeal considers the merits of plaintiffs' theories of liability. The first bellwether trial in California federal court is scheduled to begin in April 2024. We intend to vigorously defend ourselves in these actions. While we believe these cases are without merit, we cannot predict the ultimate outcome. If plaintiffs are successful in their claims, we could be required to pay significant monetary damages.

Government Investigation

In 2017, we received a subpoena from the U.S. Attorney's Office for the Southern District of New York requesting documents related to our promotional speaker programs for HIV. We are cooperating with this inquiry.

Qui Tam Litigation

A former sales employee filed a qui tam lawsuit against Gilead in March 2017 in U.S. District Court for the Eastern District of Pennsylvania. Following the government's decision not to intervene in the suit, the case was unsealed in December 2020. The lawsuit alleges that certain of Gilead's HCV sales and marketing activities violated the federal False Claims Act and various state false claims acts. The lawsuit seeks all available relief under these statutes.

Health Choice Advocates, LLC ("Health Choice") filed a qui tam lawsuit against Gilead in April 2020 in New Jersey state court. Following the New Jersey Attorney General's Office's decision not to intervene in the suit, Health Choice served us with their original complaint in August 2020. The lawsuit alleges that Gilead violated the New Jersey False Claims Act through our clinical educator programs for Sovaldi and Harvoni and our HCV and HIV patient access programs. The lawsuit seeks all available relief under the New Jersey False Claims Act. In April 2021, the trial court granted our motion to dismiss with prejudice. Health Choice has appealed the trial court's dismissal.

Health Choice filed another qui tam lawsuit against Gilead in May 2020 making similar allegations in Texas state court. Following the Texas Attorney General's Office's decision not to intervene in the suit, Health Choice served us with their original complaint in October 2020. The lawsuit alleges that Gilead violated the Texas Medicare Fraud Prevention Act ("TMFPA") through our clinical educator programs for Sovaldi and Harvoni and our HCV and HIV patient access programs. The lawsuit seeks all available relief under the TMFPA. This case was stayed in September 2021, which was lifted in April 2023.

We intend to vigorously defend ourselves in these actions. While we believe these cases are without merit, we cannot predict the ultimate outcomes. If any of these plaintiffs are successful in their claims, we could be required to pay significant monetary damages.

Securities Litigation

Immunomedics and several of its former officers and directors have been named as defendants in putative class actions filed in 2018 and 2019, which were consolidated in September 2019 in the U.S. District Court for the District of New Jersey. Plaintiffs filed a consolidated complaint in November 2019 and an amended complaint in July 2021. Plaintiffs allege that Immunomedics and the individual defendants violated the federal securities laws in connection with Immunomedics' Biologics License Application for Trodelvy, and seek certification of a class of shareholders, damages and other relief. In June 2023, the District Court entered an order approving a settlement that resolves this litigation, entering a final judgment and dismissing the litigation with prejudice.

Other Matters

We are a party to various legal actions that arose in the ordinary course of our business. We do not believe that these other legal actions will have a material adverse impact on our consolidated financial position, results of operations or cash flows.

11. EARNINGS PER SHARE

The following table shows the calculation of basic and diluted earnings per share attributable to Gilead:

(in millions, except per share amounts)	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Net income attributable to Gilead	\$ 1,045	\$ 1,144	\$ 2,055	\$ 1,163
Shares used in basic earnings per share attributable to Gilead calculation	1,249	1,256	1,249	1,255
Dilutive effect of stock options and equivalents	9	4	11	5
Shares used in diluted earnings per share attributable to Gilead calculation	1,258	1,260	1,260	1,261
Basic earnings per share attributable to Gilead	\$ 0.84	\$ 0.91	\$ 1.65	\$ 0.93
Diluted earnings per share attributable to Gilead	\$ 0.83	\$ 0.91	\$ 1.63	\$ 0.92

Potential shares of common stock excluded from the computation of diluted earnings per share attributable to Gilead because their effect would have been antidilutive were 5 million and 3 million for the three and six months ended June 30, 2023, respectively, and 20 million and 17 million, for the three and six months ended June 30, 2022, respectively.

12. INCOME TAXES

The following table summarizes our Income tax expense:

(in millions, except percentages)	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Income before income taxes	\$ 1,588	\$ 1,503	\$ 2,888	\$ 1,351
Income tax expense	\$ (549)	\$ (368)	\$ (865)	\$ (204)
Effective tax rate	34.6 %	24.5 %	29.9 %	15.1 %

Our effective income tax rate of 34.6% and 29.9% for the three and six months ended June 30, 2023, respectively, are higher than the U.S. federal statutory rate of 21% primarily due to remeasurement of certain deferred tax liabilities related to acquired intangible assets and non-deductible acquired IPR&D expenses recorded in connection with our second quarter 2023 acquisition of XinThera and first quarter 2023 acquisition of Tmunity.

Our effective income tax rate of 24.5% for the three months ended June 30, 2022 is higher than the U.S. federal statutory rate of 21% primarily due to unfavorable changes in the fair value of our equity investments that are non-deductible for income tax purposes.

Our effective income tax rate of 15.1% for the six months ended June 30, 2022 is lower than the U.S. federal statutory rate of 21% primarily due to a decrease in state deferred tax liabilities associated with a partial IPR&D impairment charge of \$2.7 billion, partially offset by unfavorable changes in the fair value of our equity investments that are non-deductible for income tax purposes.

Our income tax returns are subject to audit by federal, state and foreign tax authorities. We are currently under examination by the Internal Revenue Service for our 2016 to 2018 tax years. There are differing interpretations of tax laws and regulations, and as a result, significant disputes may arise with these tax authorities involving issues of the timing and amount of deductions and allocations of income among various tax jurisdictions. We periodically evaluate our exposures associated with our tax filing positions.

As of June 30, 2023, we believe that it is reasonably possible that our unrecognized tax benefits may decrease by approximately \$500 million in the next 12 months due to potential resolutions with a taxing authority.

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

The following discussion and analysis is intended to provide material information around events and uncertainties known to management relevant to an assessment of the financial condition and results of operations of Gilead and should therefore be read in conjunction with our audited Consolidated Financial Statements and the related notes thereto and other disclosures included as part of our Annual Report on Form 10-K for the year ended December 31, 2022 and our unaudited Condensed Consolidated Financial Statements for the three and six months ended June 30, 2023 and the related notes thereto and other disclosures (including the disclosures under Part II, Item 1A. Risk Factors) included in this Quarterly Report on Form 10-Q where other material events and uncertainties not otherwise discussed below are disclosed.

Management Overview

Gilead Sciences, Inc. ("Gilead," "we," "our" or "us") is a biopharmaceutical company that has pursued and achieved breakthroughs in medicine for more than three decades, with the goal of creating a healthier world for all people. We are committed to advancing innovative medicines to prevent and treat life-threatening diseases, including HIV, viral hepatitis, coronavirus disease 2019 ("COVID-19"), and cancer. We operate in more than 35 countries worldwide, with headquarters in Foster City, California.

Key Business Updates

The following updates are based on press releases recently issued since our last quarterly report. Readers are encouraged to review all press releases available on our website at www.gilead.com. The content on the referenced website does not constitute a part of and is not incorporated by reference into this Quarterly Report on Form 10-Q.

Virology

- Received U.S. Food and Drug Administration ("FDA") and European Commission ("EC") approval to extend the use of Veklury to treat COVID-19 in people with severe renal impairment, including those on dialysis.
- Received full marketing authorization from EC for Hepcludex (bulevirtide) for the treatment of adults with chronic hepatitis delta virus ("HDV") and compensated liver disease. Hepcludex was initially granted conditional marketing authorization in July 2020. Bulevirtide remains the only approved treatment for HDV in the EU and is not approved in the U.S.

Oncology

- Announced that the Phase 3 ENHANCE study in higher-risk myelodysplastic syndromes ("MDS") has been discontinued due to futility based on a planned analysis. The safety data seen in this study is consistent with the known magrolimab profile and adverse events that are typical in this patient population. Magrolimab is an anti-CD47 immunotherapy with a clinical development program spanning ten potential indications including ongoing trials in solid tumors and two pivotal trials: ENHANCE-2 study in acute myeloid leukemia ("AML") with TP53 mutations and ENHANCE-3 in first-line, unfit AML.
- Received EC approval for Trodelvy as monotherapy for the treatment of adult patients with unresectable or metastatic hormone receptor-positive, human epidermal growth factor receptor 2-negative ("HR+/HER2-") breast cancer who have received endocrine-based therapy, and at least two additional systemic therapies in the advanced setting.
- Announced, through Fosun Kite Biotechnology Co., Ltd., a joint venture between Kite and Shanghai Fosun Pharmaceutical (Group) Co., Ltd., the approval of axicabtagene ciloleucel (under the trade name Yikaida®) by the China National Medical Products Administration for the treatment of adult patients with relapsed or refractory ("R/R") large B-cell lymphoma ("LBCL") who failed first-line immunochemotherapy or relapsed within 12 months after first-line immunochemotherapy.
- Completed the transfer of Yescarta's marketing authorization in Japan from Daiichi Sankyo Co., Ltd. to Gilead Sciences K.K.
- Announced the acquisition of XinThera, Inc. ("XinThera"), adding additional pipeline assets including rights to a portfolio of small molecule inhibitors targeting PARP1 for oncology as well as MK2 for inflammatory diseases.

Inflammation

- Announced expansion of the Arcus Biosciences, Inc. ("Arcus") collaboration to include research programs in inflammatory diseases.

Key Financial Results

(in millions, except percentages and per share amounts)	Three Months Ended June 30,			Change	Six Months Ended June 30,			Change
	2023	2022			2023	2022		
Total revenues	\$ 6,599	\$ 6,260		5 %	\$ 12,951	\$ 12,850		1 %
Net income attributable to Gilead	\$ 1,045	\$ 1,144		(9) %	\$ 2,055	\$ 1,163		77 %
Diluted earnings per share attributable to Gilead	\$ 0.83	\$ 0.91		(9) %	\$ 1.63	\$ 0.92		77 %

Total revenues increased by 5% and 1% to \$6.6 billion and \$13.0 billion for the three and six months ended June 30, 2023, respectively, compared to the same periods in 2022, primarily due to higher product sales in HIV and Oncology, partially offset by lower sales of Veklury.

Net income attributable to Gilead was \$1.0 billion, or \$0.83 diluted earnings per share, for the three months ended June 30, 2023, compared to \$1.1 billion, or \$0.91 diluted earnings per share, for the same period in 2022. The decrease was primarily due to a \$525 million litigation accrual for settlements with certain plaintiffs in the HIV antitrust litigation, as well as other higher operating costs and tax expense, partially offset by higher product revenues and unrealized gains on equity investments compared to unrealized losses in 2022.

Net income attributable to Gilead was \$2.1 billion, or \$1.63 diluted earnings per share, for the six months ended June 30, 2023, compared to \$1.2 billion, or \$0.92 diluted earnings per share, for the same period in 2022. The increase was primarily due to a \$2.7 billion in-process research and development ("IPR&D") impairment recorded in the first quarter of 2022, which did not repeat in 2023, lower unrealized losses on equity investments and higher product revenues, partially offset by higher tax expense and higher operating costs, including the \$525 million litigation accrual for settlements with certain plaintiffs in the HIV antitrust litigation.

Results of Operations

Revenues

The following table summarizes the period-over-period changes in our Total revenues:

(in millions, except percentages)	Three Months Ended June 30, 2023				Three Months Ended June 30, 2022				Change
	U.S.	Europe	Other International	Total	U.S.	Europe	Other International	Total	
Product sales:									
HIV	\$ 3,778	\$ 521	\$ 326	\$ 4,626	\$ 3,383	\$ 562	\$ 282	\$ 4,228	9 %
Oncology	462	215	51	728	366	141	21	527	38 %
Cell Therapy	272	162	34	469	246	105	17	368	27 %
Trodelvy	189	53	17	260	120	35	3	159	63 %
Liver Disease	356	131	225	711	363	124	195	682	4 %
Chronic hepatitis C virus ("HCV")	259	95	98	452	263	94	91	448	1 %
Chronic hepatitis B virus ("HBV") / HDV	97	35	127	259	100	30	104	234	11 %
Veklury	97	52	107	256	41	126	278	445	(43) %
Other	85	80	78	243	101	88	67	256	(5) %
Total product sales	4,777	999	788	6,564	4,254	1,042	842	6,138	7 %
Royalty, contract and other revenues	6	28	1	35	85	34	2	122	(71) %
Total revenues	\$ 4,784	\$ 1,027	\$ 789	\$ 6,599	\$ 4,339	\$ 1,076	\$ 844	\$ 6,260	5 %

(in millions, except percentages)	Six Months Ended June 30, 2023				Six Months Ended June 30, 2022				Change
	U.S.	Europe	Other International	Total	U.S.	Europe	Other International	Total	
Product sales:									
HIV	\$ 7,142	\$ 1,049	\$ 624	\$ 8,816	\$ 6,245	\$ 1,112	\$ 577	\$ 7,935	11 %
Oncology	893	417	88	1,398	658	258	32	947	48 %
Cell Therapy	542	310	65	916	418	197	27	642	43 %
Trodelvy	351	107	23	482	240	61	5	305	58 %
Liver Disease	674	271	441	1,386	642	247	427	1,317	5 %
HCV	491	209	197	897	462	189	196	847	6 %
HBV / HDV	183	62	244	489	180	57	232	470	4 %
Veklury	349	163	317	829	843	430	708	1,980	(58) %
Other	153	152	137	442	195	169	129	493	(10) %
Total product sales	9,211	2,052	1,607	12,870	8,582	2,216	1,873	12,672	2 %
Royalty, contract and other revenues	25	54	3	81	112	61	5	178	(54) %
Total revenues	\$ 9,236	\$ 2,106	\$ 1,610	\$ 12,951	\$ 8,694	\$ 2,277	\$ 1,878	\$ 12,850	1 %

See Note 2. Revenues of the Notes to Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q for further disaggregation of revenue by product.

HIV

HIV product sales increased by 9% and 11% to \$4.6 billion and \$8.8 billion for the three and six months ended June 30, 2023, respectively, compared to the same periods in 2022, primarily due to favorable pricing dynamics and higher demand for Biktarvy and Descovy for pre-exposure prophylaxis ("PrEP"), partially offset by unfavorable foreign currency exchange impact. The increase for the three months ended June 30, 2023 was also partially offset by lower channel inventory.

Oncology

Cell Therapy

Cell Therapy product sales increased by 27% and 43% to \$469 million and \$916 million for the three and six months ended June 30, 2023, respectively, compared to the same periods in 2022, primarily due to increased Yescarta demand for the treatment of R/R LBCL and increased Tecartus demand for R/R mantle cell lymphoma and R/R adult acute lymphoblastic leukemia.

Trodelvy

Trodelvy product sales increased by 63% and 58% to \$260 million and \$482 million for the three and six months ended June 30, 2023, respectively, compared to the same periods in 2022, primarily due to the launch of the indication for pre-treated HR+/HER2- metastatic breast cancer in the U.S. and the increased adoption in metastatic triple-negative breast cancer.

Liver Disease

Liver Disease product sales increased by 4% and 5% to \$711 million and \$1.4 billion for the three and six months ended June 30, 2023, respectively, compared to the same periods in 2022, primarily due to higher demand, partially offset by unfavorable pricing dynamics.

Veklury

Veklury product sales decreased by 43% and 58% to \$256 million and \$829 million for the three and six months ended June 30, 2023, respectively, compared to the same periods in 2022, primarily due to lower demand driven by reduced hospitalization rates in all regions. Sales of Veklury generally reflect COVID-19 related rates and severity of infections and hospitalizations as well as the availability, uptake and effectiveness of vaccinations and alternative treatments for COVID-19.

Other

Other product sales were \$243 million for the three months ended June 30, 2023 and remained relatively flat compared to the same period in 2022.

Other product sales decreased by 10% to \$442 million for the six months ended June 30, 2023, compared to the same period in 2022, primarily due to lower demand for AmBisome and Letairis.

Royalty, contract and other revenues

Royalty, contract and other revenues decreased by 71% and 54% to \$35 million and \$81 million for the three and six months ended June 30, 2023, respectively, compared to the same periods in 2022, primarily due to higher milestone payments received in 2022 and lower royalty revenues in 2023 due to the impact of generic launches.

Foreign Currency Exchange Impact

We generally face exposure to movements in foreign currency exchange rates, primarily in the Euro. We use foreign currency exchange contracts to hedge a portion of our foreign currency exposures.

Of our total product sales, 27% and 31% were generated outside the U.S. for the three months ended June 30, 2023 and 2022, respectively. Foreign currency exchange, net of hedges, had an unfavorable impact on our total product sales of \$82 million for the three months ended June 30, 2023, based on a comparison using foreign currency exchange rates from three months ended June 30, 2022.

Of our total product sales, 28% and 32% were generated outside the U.S. for the six months ended June 30, 2023 and 2022, respectively. Foreign currency exchange, net of hedges, had an unfavorable impact on our total product sales of \$188 million for the six months ended June 30, 2023, based on a comparison using foreign currency exchange rates from six months ended June 30, 2022.

Costs and Expenses

The following table summarizes the period-over-period changes in our costs and expenses:

(in millions, except percentages)	Three Months Ended June 30,			Change	Six Months Ended June 30,			Change
	2023	2022			2023	2022		
Cost of goods sold	\$ 1,442	\$ 1,442		— %	\$ 2,843	\$ 2,866		(1) %
Product gross margin	78.0 %	76.5 %		152 bps	77.9 %	77.4 %		53 bps
Research and development expenses	\$ 1,407	\$ 1,102		28 %	\$ 2,854	\$ 2,280		25 %
Acquired in-process research and development expenses	\$ 236	\$ 330		(29) %	\$ 717	\$ 338		NM
In-process research and development impairment	\$ —	\$ —		NM	\$ —	\$ 2,700		NM
Selling, general and administrative expenses	\$ 1,849	\$ 1,357		36 %	\$ 3,168	\$ 2,440		30 %

NM - Not Meaningful

Product Gross Margin

Product gross margin was 78.0% and 77.9% for the three and six months ended June 30, 2023, respectively, and remained relatively flat compared to the same periods in 2022.

Research and Development Expenses

Research and development (“R&D”) expenses consist primarily of personnel costs including salaries, benefits and stock-based compensation expense, infrastructure, materials and supplies and other support costs, research and clinical studies performed by contract research organizations and our collaboration partners and other outside services.

We manage our R&D expenses by identifying the R&D activities we expect to be performed during a given period and then prioritizing efforts based on scientific data, probability of successful technical development and regulatory approval, market potential, available human and capital resources and other considerations. We regularly review our R&D activities based on unmet medical need and, as necessary, reallocate resources among our internal R&D portfolio and external opportunities that we believe will best support the long-term growth of our business. We do not track total R&D expenses by product candidate, therapeutic area or development phase.

The following table provides a breakout of expenses by major cost type:

(in millions)	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Personnel, infrastructure and other support costs	\$ 788	\$ 634	\$ 1,606	\$ 1,317
Clinical studies and other costs	619	468	1,248	964
Total	\$ 1,407	\$ 1,102	\$ 2,854	\$ 2,280

Research and development expenses increased by 28% and 25% to \$1.4 billion and \$2.9 billion for the three and six months ended June 30, 2023, respectively, compared to the same periods in 2022. Personnel, infrastructure and other support costs as well as Clinical studies and other costs both increased due to clinical activities primarily related to oncology, including progression and acceleration of trials, as well as new study launches.

Acquired In-Process Research and Development Expenses

Acquired in-process research and development expenses are recorded when incurred and reflect costs of externally-developed IPR&D projects, acquired directly in a transaction other than a business combination, that do not have an alternative future use, including upfront and milestone payments related to various collaborations and the costs of rights to IPR&D projects.

Acquired in-process research and development expenses were \$236 million and \$717 million for the three and six months ended June 30, 2023, respectively, primarily due to a \$170 million charge associated with our acquisition of XinThera in May 2023, a \$244 million charge associated with our acquisition of Tmunity Therapeutics, Inc. ("Tmunity") in February 2023 and a \$212 million upfront payment associated with the collaboration with Arcellx, Inc., which we entered into in January 2023. Acquired in-process research and development expenses were \$330 million and \$338 million for the three and six months ended June 30, 2022, respectively, primarily related to a \$300 million upfront payment for our collaboration with Dragonfly Therapeutics, Inc. See Note 6. Acquisitions, Collaborations and Other Arrangements of the Notes to Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q for additional information.

In-Process Research and Development Impairment

In-process research and development impairment was \$2.7 billion for the six months ended June 30, 2022 related to a partial impairment charge on our HR+/HER2- IPR&D intangible asset. No IPR&D impairment charges were recorded during the three and six months ended June 30, 2023.

Selling, General and Administrative Expenses

Selling, general and administrative expenses are recorded when incurred and consist primarily of personnel costs, facilities and overhead costs, outside marketing, advertising and legal expenses, and other general and administrative costs related to sales and marketing, finance, human resources, legal and other administrative activities.

Selling, general and administrative expenses increased by 36% and 30% to \$1.8 billion and \$3.2 billion for the three and six months ended June 30, 2023, respectively, compared to the same periods in 2022, primarily due to a \$525 million litigation accrual for settlements with certain plaintiffs in the HIV antitrust litigation and increased commercial activities in oncology and HIV, partially offset by a reduction in donations to the Gilead Foundation and other corporate expenses.

Interest Expense and Other Income (Expense), Net

The following table summarizes the period-over-period changes in Interest expense and Other income (expense), net:

(in millions, except percentages)	Three Months Ended June 30,		Change	Six Months Ended June 30,		Change
	2023	2022		2023	2022	
Interest expense	\$ (230)	\$ (242)	(5) %	\$ (459)	\$ (480)	(4) %
Other income (expense), net	\$ 152	\$ (284)	NM	\$ (22)	\$ (395)	(94) %

NM - Not Meaningful

Interest expense for the three and six months ended June 30, 2023 decreased by 5% and 4% to \$230 million and \$459 million, respectively, compared to the same periods in 2022, primarily due to lower outstanding debt balances.

The changes in Other income (expense), net for the three and six months ended June 30, 2023 compared to the same periods in 2022 primarily reflect net unrealized gains from equity securities during the second quarter of 2023 compared to net unrealized losses during the first quarter of 2023 and the first and second quarters of 2022, as well as higher interest income due to rising interest rates.

Income Taxes

The following table summarizes the period-over-period changes in Income tax expense:

(in millions, except percentages)	Three Months Ended June 30,			Six Months Ended June 30,		
	2023	2022	Change	2023	2022	Change
Income before income taxes	\$ 1,588	\$ 1,503	\$ 84	\$ 2,888	\$ 1,351	\$ 1,537
Income tax expense	\$ (549)	\$ (368)	\$ 181	\$ (865)	\$ (204)	\$ 660
Effective tax rate	34.6 %	24.5 %	10.1 %	29.9 %	15.1 %	14.8 %

Our effective tax rate increased for the three months ended June 30, 2023, compared to the same period in 2022, primarily due to remeasurement of certain deferred tax liabilities related to acquired intangible assets and non-deductible acquired IPR&D expenses recorded in connection with our acquisition of XinThera.

Our effective tax rate increased for the six months ended June 30, 2023, compared to the same period in 2022, primarily due to non-deductible acquired IPR&D expenses recorded in connection with our acquisition of Tmunity and a partial IPR&D impairment charge of \$2.7 billion recorded in the six months ended June 30, 2022, in addition to the above mentioned drivers for the three months ended June 30, 2023.

Liquidity and Capital Resources

We continually evaluate our liquidity and capital resources, including our access to external capital, so that we can adequately and efficiently finance our operations.

Liquidity

Cash, cash equivalents and marketable debt securities were \$8.0 billion and \$7.6 billion as of June 30, 2023 and December 31, 2022, respectively. Cash and cash equivalents increased by \$292 million from December 31, 2022 to June 30, 2023. The following table summarizes our cash flow activities:

(in millions)	Six Months Ended June 30,	
	2023	2022
Net cash provided by (used in):		
Operating activities	\$ 4,082	\$ 3,642
Investing activities	\$ (1,309)	\$ (1,378)
Financing activities	\$ (2,507)	\$ (2,797)
Effect of exchange rate changes on cash and cash equivalents	\$ 26	\$ (66)

Operating Activities

Net cash provided by operating activities is derived by adjusting our net income for non-cash items and changes in operating assets and liabilities. Net cash provided by operating activities was \$4.1 billion for the six months ended June 30, 2023 compared to \$3.6 billion for the same period in 2022. The change was primarily due to the effect of the non-recurring payment of a \$1.25 billion settlement related to bictegravir litigation in 2022, partially offset by higher inventory and operating spend in 2023.

Investing Activities

Net cash used in investing activities was \$1.3 billion for the six months ended June 30, 2023 compared to \$1.4 billion for the same period in 2022. The change was primarily due to a decrease in acquisition spend, including acquired IPR&D, and capital expenditures, partially offset by higher net purchases of marketable debt and equity securities.

Financing Activities

Net cash used in financing activities was \$2.5 billion for the six months ended June 30, 2023 compared to \$2.8 billion for the same period in 2022. During the six months ended June 30, 2023, we utilized cash of \$1.9 billion for dividend payments and \$550 million for common stock repurchases. During the six months ended June 30, 2022, we utilized cash of \$500 million for debt repayments, \$1.9 billion for dividend payments and \$424 million for common stock repurchases.

Capital Resources and Material Cash Requirements

A summary of our capital resources and material cash requirements is presented in Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2022. See Notes 6. Acquisitions, Collaborations and Other Arrangements, 9. Debt and Credit Facilities, 10. Commitments and Contingencies and 12. Income Taxes of the Notes to Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q for any material changes to our capital resources and material cash requirements during the six months ended June 30, 2023.

Critical Accounting Estimates

A summary of our critical accounting estimates is presented in Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2022. There were no material changes to our critical accounting estimates during the six months ended June 30, 2023.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Information about our market risk is presented in Part II, Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2022. See Notes 3. Fair Value Measurements, 4. Available-For-Sale Debt Securities and Equity Securities and 5. Derivative Financial Instruments of the Notes to Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q for any material changes to these disclosures.

Item 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

An evaluation as of June 30, 2023 was carried out under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our “disclosure controls and procedures,” which are defined in Rule 13a-15(e) under the U.S. Securities Exchange Act of 1934, as amended (the “Exchange Act”), as controls and other procedures of a company that are designed to ensure that the information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in U.S. Securities and Exchange Commission’s rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of June 30, 2023.

Changes in Internal Control over Financial Reporting

Our management, including our Chief Executive Officer and Chief Financial Officer, has evaluated any changes in our internal control over financial reporting that occurred during the quarter ended June 30, 2023, and has concluded that there was no change during such quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. We anticipate implementing a new enterprise resource planning (“ERP”) system beginning in August 2023. Along with this implementation, which is scheduled to occur in phases over the next few years, we anticipate making changes to our internal controls over financial reporting to address processes impacted by the new ERP system. As such changes occur, we will evaluate quarterly whether such changes materially affect our internal control over financial reporting.

Limitations on the Effectiveness of Controls

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within a company have been detected. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met and, as set forth above, our Chief Executive Officer and Chief Financial Officer have concluded, based on their evaluation as of the end of the period covered by this report, that our disclosure controls and procedures were effective to provide reasonable assurance that the objectives of our disclosure control system were met.

PART II OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

For a description of our significant pending legal proceedings, please see Note 10. Commitments and Contingencies of the Notes to Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Item 1A. RISK FACTORS

In evaluating our business, you should carefully consider the following discussion of material risks, events and uncertainties that make an investment in us speculative or risky in addition to the other information in this Quarterly Report on Form 10-Q. A manifestation of any of the following risks and uncertainties could, in circumstances we may or may not be able to accurately predict, materially and adversely affect our business and operations, growth, reputation (including the commercial or scientific reputation of our products), prospects, product pipeline and sales, operating and financial results, financial condition, cash flows, liquidity and stock price. We note these factors for investors as permitted by the Private Securities Litigation Reform Act of 1995. It is not possible to predict or identify all such factors; our operations could also be affected by factors, events or uncertainties that are not presently known to us or that we currently do not consider to present significant risks to our operations. Therefore, you should not consider the following risks to be a complete statement of all the potential risks or uncertainties that we face.

Product and Commercialization Risks

Certain of our products subject us to additional or heightened risks.

HIV

We receive a substantial portion of our revenue from sales of our products for the treatment and prevention of HIV infection. During the six months ended June 30, 2023, sales of our HIV products accounted for approximately 68% of our total product sales. We may be unable to sustain or increase sales of our HIV products for any number of reasons, including market share gains by competitive products, including generics, or the inability to introduce new HIV medications necessary to remain competitive. In such case, we may need to scale back our operations, including our future drug development and spending on research and development (“R&D”) efforts. For example, many of our HIV products contain tenofovir alafenamide (“TAF”), which belongs to the nucleoside class of antiviral therapeutics. If there are any changes to the treatment or prevention paradigm for HIV that cause nucleoside-based therapeutics to fall out of favor, our HIV product sales would be adversely impacted.

Veklury

We face risks related to our supply and sale of Veklury, which was approved by U.S. Food and Drug Administration (“FDA”) as a treatment for patients with coronavirus disease 2019 (“COVID-19”). Veklury sales generally reflect COVID-19 related rates and severity of infections and hospitalizations, as well as the availability, uptake and effectiveness of vaccines and alternative treatments for COVID-19. In May 2023, the World Health Organization declared the end of COVID-19 as a public health emergency of international concern. Future sales of Veklury in the short- and long-term remain uncertain. If we do not accurately forecast demand or manufacture Veklury at levels to align with actual demand, then we may experience product shortages or build excess inventory that may need to be written off.

Cell Therapy

Advancing a novel and personalized therapy such as Yescarta or Tecartus, which are chimeric antigen receptor (“CAR”) T-cell therapies, creates significant challenges, including:

- educating and certifying medical personnel regarding the procedures and the potential side effects, such as cytokine release syndrome and neurologic toxicities, in compliance with the Risk Evaluation and Mitigation Strategy program required by FDA;
- securing sufficient supply of other medications to manage side effects, such as tocilizumab and corticosteroids, which may not be available in sufficient quantities, may not adequately control the side effects and/or may have detrimental impacts on the efficacy of cell therapy;
- developing and maintaining a robust and reliable process for engineering a patient’s T cells in our facilities and infusing them back into the patient; and
- conditioning patients with chemotherapy in advance of administering our therapy, which may increase the risk of adverse side effects.

The use of engineered T cells as a potential cancer treatment is a recent development and may not be broadly accepted by physicians, patients, hospitals, cancer treatment centers, payers and others in the medical community. While FDA has approved some cell therapies, including Yescarta and Tecartus, we must continue to demonstrate to the medical community the potential advantages of cell therapy compared to existing and future therapeutics. For challenges related to the reimbursement of Yescarta and Tecartus, see also “Our existing products are subject to reimbursement pressures from government agencies and other third parties, required rebates and other discounts on our products and other pricing pressures.”

We rely on third-party sites to collect patients’ white blood cells, known as apheresis centers, as well as shippers, couriers, and hospitals for the logistical collection of patients’ white blood cells and ultimate delivery of Yescarta and Tecartus to patients. These vendors may encounter disruptions or difficulties that could result in product loss and regulatory action. Apheresis centers may also choose not to participate in our quality certification process, or we may be unable to complete such certification in a timely manner or at all, which could delay or constrain our manufacturing and commercialization efforts.

We operate an automated CAR T-cell therapy manufacturing facility in Frederick, Maryland. We have not previously manufactured our products in an automated facility on a commercial scale, and as a result, we may require additional time and resources in order to effectively increase manufacturing capacity. We also operate a retroviral vector manufacturing facility in Oceanside, California, which received FDA approval for commercial production in October 2022. We also have not previously manufactured viral vectors on a commercial scale, and as a result, we may require additional time and resources in order to effectively increase manufacturing capacity. In addition, we may not be able to produce or otherwise obtain an amount of viral vector supply sufficient to satisfy demand for our finished products. If we are unable to meet product demand, we will have difficulty meeting sales forecasts for our finished products.

Our success depends on developing and commercializing new products or expanding the indications for existing products.

If we are unable to launch commercially successful new products or new indications for existing products, our business will be adversely impacted. The launch of commercially successful products is necessary to grow our business, cover our substantial R&D expenses, and offset revenue losses when existing products lose market share due to factors such as competition and loss of patent exclusivity. There are many difficulties and uncertainties inherent in drug development and the introduction of new products. The product development cycle is characterized by significant investments of resources, long lead times and unpredictable outcomes due to the nature of developing medicines for human use. We expend significant time and resources on our product pipeline without any assurance that we will recoup our investments or that our efforts will be commercially successful. A high rate of failure is inherent in the discovery and development of new products, and failure can occur at any point in the process, including late in the process after substantial investment.

We face challenges in accurately forecasting sales because of the difficulties in predicting demand for our products and fluctuations in purchasing patterns or wholesaler inventories.

We may be unable to accurately predict demand for our products, including the uptake of new products, as demand depends on a number of factors. For example, product demand may be adversely affected if physicians do not see the benefit of our products. Additionally, the non-retail sector in the U.S., which includes government institutions, including state AIDS Drug Assistance Programs, the U.S. Department of Veterans Affairs, correctional facilities and large health maintenance organizations, tends to be less consistent in terms of buying patterns and often causes quarter-over-quarter fluctuations that do not mirror actual patient demand for our products. Federal and state budget pressures, as well as the annual grant cycles for federal and state funds, may cause purchasing patterns to not reflect patient demand for our products. We expect to continue to experience fluctuations in the purchasing patterns of our non-retail customers. In light of the budget crises faced by many European countries, we have observed variations in purchasing patterns induced by cost containment measures in Europe. We believe these measures have caused some government agencies and other purchasers to reduce inventory of our products in the distribution channels, and we may continue to see this trend in the future.

We sell and distribute most of our products in the U.S. exclusively through the wholesale channel. For the six months ended June 30, 2023, approximately 90% of our product sales in the U.S. were to three wholesalers, AmerisourceBergen Corporation, Cardinal Health, Inc. and McKesson Corporation. The U.S. wholesalers with whom we have entered into inventory management agreements make estimates to determine end-user demand and may not be accurate in matching their inventory levels to actual end-user demand. As a result, changes in inventory levels held by those wholesalers can cause our operating results to fluctuate unexpectedly if our sales to these wholesalers do not match end-user demand. In addition, inventory is held at retail pharmacies and other non-wholesaler locations with whom we have no inventory management agreements and no control over buying patterns. Adverse changes in economic conditions, increased competition or other factors may cause retail pharmacies to reduce their inventories of our products, which would reduce their orders from wholesalers and, consequently, the wholesalers’ orders from us, even if end-user demand has not changed. In addition, we have observed that strong wholesaler and sub-wholesaler purchases of our products in the fourth quarter typically results in inventory draw-down by wholesalers and sub-wholesalers in the subsequent first quarter. As inventory in the distribution channel fluctuates from quarter to quarter, we may continue to see fluctuations in our earnings and a mismatch between prescription demand for our products and our revenues.

We face significant competition from global pharmaceutical and biotechnology companies, specialized pharmaceutical firms and generic drug manufacturers.

New branded or generic products entering major markets affects our ability to maintain pricing and market share. Our products compete with other available products based primarily on efficacy, safety, tolerability, acceptance by doctors, ease of patient compliance, ease of use, price, insurance and other reimbursement coverage, distribution and marketing. A number of companies are pursuing the development of products and technologies that may be competitive with our existing products or research programs. These competing companies include large pharmaceutical and biotechnology companies and specialized pharmaceutical firms acting either independently or together with other such companies. Furthermore, academic institutions, government agencies and other public and private organizations conducting research may seek patent protection or may establish collaborative arrangements for competitive products or programs. We may be adversely impacted if any of these competitors gain market share as a result of new technologies, commercialization strategies or otherwise.

Our existing products are subject to reimbursement pressures from government agencies and other third parties, required rebates and other discounts on our products and other pricing pressures.

Product Reimbursements

Successful commercialization of our products depends, in part, on the availability and amount of third-party payer reimbursement for our products and related treatments and medical services in the markets where we sell our products. As our products mature, pricing pressures from private insurers and government payers often result in a reduction of the net product prices.

Legislative and regulatory actions affecting government prescription drug procurement and reimbursement programs occur relatively frequently. For example, in September 2020, FDA issued a final rule implementing a pathway for the importation of certain prescription drugs from Canada. This rule is subject to ongoing litigation. We may be adversely impacted by any such legislative and regulatory actions, though it is difficult to predict the impact, if any, on the use and reimbursement of our products.

Product Pricing, Discounts and Rebates

In the U.S., the European Union (“EU”) and other significant or potentially significant markets for our products and product candidates, government authorities and third-party payers are increasingly attempting to limit or regulate the price of medical products and services. The volume of drug pricing-related legislation has dramatically increased in recent years, including:

- U.S. Congress has enacted laws requiring manufacturer refunds on certain amounts of discarded drug from single-use vials beginning in 2023 and eliminating the existing cap on Medicaid rebate amounts beginning in 2024.
- U.S. Congress has enacted the Inflation Reduction Act of 2022 (the “Act”), which, among other changes, (1) requires the Department of Health and Human Services to “negotiate” Medicare prices for certain drugs (starting with 10 drugs in 2026, adding 15 drugs in 2027 and 2028, and adding 20 drugs in 2029 and subsequent years), (2) imposes an inflation-based rebate on Medicare Part B utilization starting in 2023 and Part D utilization beginning October 1, 2022, and (3) restructures the Medicare Part D benefit to cap out-of-pocket expenses for Part D beneficiaries beginning in 2024 and, effective January 1, 2025, increases Part D plans’ contributions in the catastrophic coverage phase and increases manufacturers’ discount contributions across coverage phases such that manufacturers must pay a 10% discount in the initial coverage phase and a 20% discount in the catastrophic phase on drugs utilized by all Part D beneficiaries, including low income subsidy patients. We continue to evaluate the potential impact of the Act on our business. Centers for Medicare & Medicaid Services (“CMS”) has issued a number of guidance documents but how certain provisions will be implemented remains unclear. Additional guidance, legislation or rulemaking may be issued that could reflect the government’s evolving views. In addition, several manufacturers and trade organizations have challenged the Medicare “negotiation” provisions of the Act, and additional legal challenges may be filed in the future. While the full impact of the Act on our business and the pharmaceutical industry remains uncertain at this time, we anticipate that the Act will increase our payment obligations under the redesigned Part D discount program, limit the prices we can charge for our products, and increase the rebates we must provide government programs for our products, thereby reducing our profitability and negatively impacting our financial results.
- Many state legislatures are considering, or have already passed into law, legislation that seeks to indirectly or directly regulate pharmaceutical drug pricing, such as requiring manufacturers to publicly report proprietary pricing information, creating review boards for prices, establishing drug payment limits, and encouraging the use of generic drugs. These initiatives and such other legislation may cause added pricing pressures on our products, and the resulting impact on our business is uncertain.

- Many countries outside the U.S., including the EU member states, have established complex and lengthy procedures to obtain price approvals and coverage reimbursement and periodically review their pricing and reimbursement decisions. The outcome of these reviews cannot be predicted and could have an adverse effect on the pricing and reimbursement of our medical products in the EU member states. Reductions in the pricing of our medical products in one member state could affect the price in other member states and have a negative impact on our financial results.

A substantial portion of our product sales is subject to significant discounts from list price, including rebates that we may be required to pay state Medicaid agencies and discounts provided to covered entities under Section 340B of the Public Health Service Act (“340B”). Changes to the 340B program or the Medicaid program at the federal or state level could have a material adverse effect on our business. For example, the continued growth of the 340B program limits the prices we may charge on an increasing percentage of sales. Changes to the calculation of rebates under the Medicaid program could substantially increase our Medicaid rebate obligations and decrease the prices we charge 340B-covered entities.

In March 2022, we implemented a contract pharmacy integrity initiative for our branded hepatitis C virus (“HCV”) products. This integrity initiative does not involve any products from Asegu Therapeutics LLC. Our integrity initiative requires covered entities that enter into 340B bill to/ship to arrangements with contract pharmacies for our branded HCV products to provide claims level data for units dispensed from such contract pharmacies; covered entities without an in-house pharmacy that choose not to participate in the initiative can designate a single contract pharmacy for shipment. Certain manufacturers that have implemented other contract pharmacy integrity programs have received enforcement letters from the U.S. Department of Health and Human Services (“HHS”) asserting that those programs violate the 340B statute, have been referred to the HHS Office of Inspector General for assessment of civil monetary penalties, and have been subject to administrative dispute resolution proceedings brought on behalf of covered entities. These manufacturers are currently challenging HHS’ position in ongoing litigation. We believe that our integrity initiative complies with the requirements of the 340B statute. However, additional legal or legislative developments with respect to the 340B program, including potential litigation with HHS, may negatively impact our ability to implement or continue our integrity initiative.

In addition, standard reimbursement structures may not adequately reimburse for innovative therapies. For example, beginning in fiscal year 2021, CMS established a new severity-adjusted diagnosis-related group (“DRG”) 018 for Medicare inpatient reimbursement of CAR T-cell products such as Yescarta and Tecartus. While the new DRG has a significantly higher base payment amount than the prior DRG 016, the payment available may not be sufficient to reimburse some hospitals for their cost of care for patients receiving Yescarta and Tecartus. When reimbursement is not aligned well to account for treatment costs, Medicare beneficiaries may be denied access as this misalignment could impact the willingness of some hospitals to offer the therapy and of doctors to recommend the therapy. Additionally, in the EU, there are barriers to reimbursement in individual countries that could limit the uptake of Yescarta and Tecartus.

Moreover, we estimate the rebates we will be required to pay in connection with sales during a particular quarter based on claims data from prior quarters. In the U.S., actual rebate claims are typically made by payers one to three quarters in arrears. Actual claims and payments may vary significantly from our estimates.

We may experience adverse impacts resulting from the importation of our products from lower price markets or the distribution of illegally diverted or counterfeit versions of our products.

Prices for our products are based on local market economics and competition and sometimes differ from country to country. Our sales in countries with relatively higher prices may be reduced if products can be imported and resold into those countries from lower price markets. U.S. sales could also be affected if FDA permits importation of drugs from Canada. We have entered into agreements with generic drug manufacturers as well as licensing agreements with the Medicines Patent Pool, a United Nations-backed public health organization, which allow generic drug manufacturers to manufacture generic versions of certain of our products for distribution in certain low- and middle-income countries. We may be adversely affected if any generic versions of our products, whether or not produced and/or distributed under these agreements, are exported to the U.S., the EU or markets with higher prices.

In the EU, we are required to permit products purchased in one EU member state to be sold in another member state. Purchases of our products in member states where our selling prices are relatively low for resale in member states in which our selling prices are relatively high can affect the inventory level held by our wholesalers and can cause the relative sales levels in the various countries to fluctuate from quarter to quarter and not reflect the actual consumer demand in any given quarter.

Additionally, diverted products may be used in countries where they have not been approved and patients may source the diverted products outside the legitimate supply chain. These diverted products may be handled, shipped and stored inappropriately, which may affect the quality and/or efficacy of the products and could harm patients and adversely impact us.

We are also aware of the existence of various suppliers around the world that, without Gilead’s authorization, purport to source our products and generic versions of our products and sell them for use in countries where those products have not been approved. As a result, patients may be at risk of taking unapproved medications that may not be what they purport to be, may not have the potency they claim to have or may contain harmful substances, which could harm patients and adversely impact us.

Further, third parties have illegally distributed and sold, and may continue to illegally distribute and sell, illegally diverted and counterfeit versions of our medicines, which do not meet the rigorous quality standards of our manufacturing and supply chain. For example, as part of a U.S. civil enforcement lawsuit in coordination with law enforcement, and pursuant to court order, we seized thousands of bottles of Gilead-labeled medication with counterfeit supply chain documentation. Our investigation revealed that pharmaceutical distributors that are not authorized by Gilead to sell Gilead medicine sold purportedly genuine Gilead medicine sourced from an illegal counterfeiting scheme to independent pharmacies nationwide.

Illegally diverted and counterfeit versions of Gilead-branded medicines exist and may pose a serious risk to patient health and safety. Our actions to stop or prevent the distribution and sale of illegally diverted and counterfeit versions of our medicines around the world may be costly and unsuccessful, which may adversely affect patients and our reputation and business, including our product revenues and financial results.

Product Development and Supply Chain Risks

We face risks in our clinical trials, including the potential for unfavorable results, delays in anticipated timelines and disruption.

We are required to demonstrate the safety and efficacy of product candidates that we develop for each intended use through extensive preclinical studies and clinical trials. The results from these studies do not always accurately predict results in later, large-scale clinical trials. Even successfully completed large-scale clinical trials may not result in marketable products.

We face numerous risks and uncertainties with our clinical trials that could result in delays or prevent completion of the development and approval of our product candidates, including challenges in clinical trial protocol design, our ability to enroll patients in clinical trials, the possibility of unfavorable or inadequate trial results to support further development of our product candidates, including failure to meet a trial's primary endpoint, safety issues arising from our clinical trials, and the need to modify or delay our clinical trials or to perform additional trials. For example, in October 2022, we announced that FDA issued a complete response letter for our Biologics License Application for bulevirtide for the treatment of adults with hepatitis delta virus infection. In addition, see Note 7. Intangible Assets of the Condensed Consolidated Financial Statements included in Part I, Item I of this Quarterly Report on Form 10-Q for a discussion of the partial in-process research and development impairment charge that we recognized during the three months ended March 31, 2022 related to assets we acquired from Immunomedics, Inc. ("Immunomedics") in 2020.

As a result, we may be unable to successfully complete our clinical trials on our anticipated timelines, or at all. Based on trial results, it is possible that FDA and other regulatory authorities do not approve our product candidates, or that any market approvals include significant limitations on the products' use. In addition, clinical trials involving our commercial products can raise new safety issues for our existing products, which could adversely impact our business. Further, we may make a strategic decision to discontinue development of our product candidates if, for example, we believe commercialization will be difficult relative to other opportunities in our pipeline. Therefore, our product candidates may never be successfully commercialized, and we may be unable to recoup the significant R&D and clinical trial expenses incurred. We expect to expend significant time and resources on our clinical trial activities without any assurance that we will recoup our investments or that our efforts will be commercially successful.

There are also risks associated with the use of third parties in our clinical trial activities. We extensively outsource our clinical trial activities and usually perform only a small portion of the start-up activities in-house. We rely on independent third-party contract research organizations ("CROs") to perform most of our clinical studies, including document preparation, site identification, screening and preparation, pre-study visits, training, program management, patient enrollment, ongoing monitoring, site management and bioanalytical analysis. Many important aspects of the services performed for us by the CROs are out of our direct control. If there is any dispute or disruption in our relationship with our CROs, our clinical trials may be delayed. Moreover, in our regulatory submissions, we rely on the quality and validity of the clinical work performed by third-party CROs. If any of our CROs' processes, methodologies or results were determined to be invalid or inadequate, our own clinical data and results and related regulatory approvals may be adversely affected.

We may face manufacturing difficulties, delays or interruptions, including at our third-party manufacturers and corporate partners.

Our products, which are manufactured at our own facilities or by third-party manufacturers and corporate partners, are the result of complex, highly regulated manufacturing processes. We depend on third-party manufacturers and corporate partners to perform manufacturing activities effectively and on a timely basis for the majority of our active pharmaceutical ingredients and drug products. These third parties are independent entities subject to their own unique operational and financial risks that are out of our control. We and our third-party manufacturers and corporate partners are subject to Good Manufacturing Practices ("GMP"), which are extensive regulations governing manufacturing processes, stability testing, record keeping and quality standards as defined by FDA and European Medicines Agency ("EMA"), as well as comparable regulations in other jurisdictions. Manufacturing operations are also subject to routine inspections by regulatory agencies.

Any adverse developments affecting or resulting from our manufacturing operations or the operations of our third-party manufacturers and corporate partners may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls or other interruptions in the commercial supply of our products. We have incurred, and will continue to incur, inventory write-off charges and other expenses for products that fail to meet specifications and quality standards, and we may need to undertake costly remediation efforts or seek more costly manufacturing alternatives. Such developments could increase our manufacturing costs, cause us to lose revenues or market share and damage our reputation. In addition, manufacturing issues may cause delays in our clinical trials and applications for regulatory approval. For example, if we are unable to remedy any deficiencies cited by FDA or other regulatory agencies in their inspections, our existing products and the timing of regulatory approval of product candidates in development could be adversely affected. Further, there is risk that regulatory agencies in other countries where marketing applications are pending will undertake similar additional reviews or apply a heightened standard of review, which could delay the regulatory approvals for products in those countries. Our business may be adversely affected if approval of any of our product candidates were delayed or if production of our products were interrupted.

We may not be able to obtain materials or supplies necessary to conduct clinical trials or to manufacture and sell our products, which could limit our ability to generate revenues.

We need access to certain supplies and products to conduct our clinical trials and to manufacture and sell our products. If we are unable to purchase enough of these materials or find suitable alternative materials in a timely manner, our development efforts for our product candidates may be delayed or our ability to manufacture and sell our products could be limited. For example, in the U.S., there is currently a shortage of certain cancer drugs that are the backbone of standard-of-care treatments, such as carboplatin and cisplatin, which are also used in research and development and clinical trials. While we have observed minimal impacts to our oncology clinical trials to date, if these shortages continue or increase in magnitude, our ongoing and future oncology clinical trials may be delayed, halted or adversely impacted.

Suppliers of key components and materials must be named in the new drug application or marketing authorization application filed with the regulatory authority for any product candidate for which we are seeking marketing approval, and significant delays can occur if the qualification of a new supplier is required. Even after a manufacturer is qualified by the regulatory authority, the manufacturer must continue to expend time, money and effort in the area of production and quality control to maintain full compliance with GMP. Manufacturers are subject to regular periodic inspections by regulatory authorities following initial approval. If, as a result of these inspections, a regulatory authority determines that the equipment, facilities, laboratories or processes do not comply with applicable regulations and conditions of product approval, the regulatory authority may suspend the manufacturing operations. If the manufacturing operations of any of the single suppliers for our products are suspended, we may be unable to generate sufficient quantities of commercial or clinical supplies of product to meet market demand. In addition, if deliveries of materials from our suppliers are interrupted for any reason, we may be unable to ship certain of our products for commercial supply or to supply our product candidates in development for clinical trials. Also, some of our products and the materials that we utilize in our operations are manufactured by only one supplier or at only one facility, which we may not be able to replace in a timely manner and on commercially reasonable terms, or at all. Problems with any of the single suppliers or facilities we depend on, including in the event of a disaster, such as an earthquake, equipment failure or other difficulty, may negatively impact our development and commercialization efforts.

A significant portion of the raw materials and intermediates used to manufacture our antiviral products are supplied by third-party manufacturers and corporate partners outside of the U.S. As a result, any political or economic factors in a specific country or region, including any changes in or interpretations of trade regulations, compliance requirements or tax legislation, that would limit or prevent third parties outside of the U.S. from supplying these materials could adversely affect our ability to manufacture and supply our antiviral products to meet market needs and have a material and adverse effect on our operating results.

If we were to encounter any of these difficulties, our ability to conduct clinical trials on product candidates and to manufacture and sell our products could be impaired.

Regulatory and Other Legal Risks

Our operations depend on compliance with complex FDA and comparable international regulations. Failure to obtain broad approvals on a timely basis or to maintain compliance could delay or halt commercialization of our products.

The products we develop must be approved for marketing and sale by regulatory authorities and, once approved, are subject to extensive regulation by FDA, EMA and comparable regulatory agencies in other countries. We have filed, and anticipate that we will continue to file, for marketing approval in additional countries and for additional indications and products. These and any future marketing applications we file may not be approved by the regulatory authorities on a timely basis, or at all. Even if marketing approval is granted for these products, there may be significant limitations on their use. We cannot state with certainty when or whether any of our product candidates under development will be approved or launched; whether we will be able to develop, license or acquire additional product candidates or products; or whether any products, once launched, will be commercially successful.

Further, how we manufacture and sell our products is subject to extensive regulation and review. For example, under FDA rules, we are often required to conduct post-approval clinical studies to assess a known serious risk, signals of serious risk or to identify an unexpected serious risk. In certain circumstances, we may be required to implement a Risk Evaluation and Mitigation Strategy program for our products, which could include a medication guide, patient package insert, a communication plan to healthcare providers, restrictions on distribution or use of a product and other elements FDA deems necessary to assure safe use of the drug. Discovery of previously unknown problems with our marketed products or product candidates, including serious safety, resistance or drug interaction issues, or problems with our manufacturing, safety reporting or promotional activities, may result in regulatory approvals being delayed, denied or granted with significant restrictions on our products, including limitations on or the withdrawal of the products from the market.

Failure to comply with these or other requirements imposed by FDA could result in significant civil monetary penalties, fines, suspensions of regulatory approvals, product recalls, seizure of products and criminal prosecutions.

We are impacted by evolving laws, regulations and legislative or regulatory actions applicable to the healthcare industry.

The healthcare industry is subject to various federal, state and international laws and regulations pertaining to drug approval, reimbursement, rebates, price reporting, healthcare fraud and abuse, and data privacy and security. In the U.S., these laws include anti-kickback and false claims laws, Federal Food, Drug, and Cosmetic Act, laws and regulations relating to the Medicare and Medicaid programs and other federal and state programs, such as the Medicaid Rebate Statute and the 340B statute, laws that regulate written and verbal communications about our products, individual state laws relating to pricing and sales and marketing practices, the Health Insurance Portability and Accountability Act and other federal and state laws relating to the privacy and security of health information. Actual or alleged violations of these laws or any related regulations may be punishable by criminal and/or civil sanctions, including, in some instances, substantial fines, civil monetary penalties, exclusion from participation in federal and state healthcare programs, including Medicare, Medicaid and U.S. Department of Veterans Affairs and U.S. Department of Defense health programs, actions against executives overseeing our business and significant remediation measures, negative publicity or other consequences. These laws and regulations are broad in scope and subject to changing and evolving interpretations, which could require us to incur substantial costs associated with compliance, alter one or more of our sales or marketing practices, or impact our ability to obtain or maintain regulatory approvals. The resulting impact on our business is uncertain and could be material.

In addition, government price reporting and payment regulations are complex, and we are continually assessing the methods by which we calculate and report pricing in accordance with these obligations. Our methodologies for calculations are inherently subjective and may be subject to review and challenge by various government agencies, which may disagree with our interpretation. If the government disagrees with our reported calculations, we may need to restate previously reported data and could be subject to additional financial and legal liability.

There also continues to be enhanced scrutiny of company-sponsored patient assistance programs, including co-pay assistance programs and manufacturer donations to third-party charities that provide such assistance. There has also been enhanced scrutiny by governments on reimbursement and other patient support offerings, clinical education programs and promotional speaker programs. If we, or our agents and vendors, are deemed to have failed to comply with laws, regulations or government guidance in any of these areas, we could be subject to criminal or civil sanctions. Any similar violations by our competitors could also negatively impact our industry reputation and increase scrutiny over our business and our products.

For a description of our government investigations and related litigation, see Note 10. Commitments and Contingencies of the Notes to Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

We are subject to risks if significant safety issues arise for our marketed products or our product candidates.

As additional studies are conducted after obtaining marketing approval for our products, and as our products are used over longer periods of time by many patients, including patients with underlying health problems or those taking other medicines, we expect to continue finding new issues related to safety, resistance or drug interactions. Any such issues may require changes to our product labels, such as additional warnings, contraindications or even narrowed indications, or to halt sales of a product.

Regulatory authorities have been moving towards more active and transparent pharmacovigilance and are making greater amounts of stand-alone safety information and clinical trial data directly available to the public through websites and other means, such as periodic safety update report summaries, risk management plan summaries and various adverse event data. Safety information, without the appropriate context and expertise, may be misinterpreted and lead to misperception or legal action.

Our success depends to a significant degree on our ability to obtain and defend our patents and other intellectual property rights both domestically and internationally, and to operate without infringing upon the patents or other proprietary rights of third parties.

Patents and other proprietary rights are very important to our business. As part of our business strategy, we actively seek patent protection both in the U.S. and internationally and file additional patent applications, when appropriate, to cover improvements in our compounds, products and technology. Our success depends to a significant degree on our ability to:

- obtain patents and licenses to patent rights;
- preserve trade secrets and internal know-how;
- defend against infringement of our patents and efforts to invalidate them; and
- operate without infringing on the intellectual property of others.

Because patent applications are confidential for a period of time after filing, we may not know if our competitors have filed applications for technology covered by our pending applications or if we were the first to invent or first to file an application directed toward the technology that is the subject of our patent applications. If competitors file patent applications covering our technology, we may have to participate in litigation, post-grant proceedings before the U.S. Patent and Trademark Office or other proceedings to determine the right to a patent or validity of any patent granted. Such litigation and proceedings are unpredictable and expensive, and could divert management attention from other operations, such that, even if we are ultimately successful, we may be adversely impacted.

Patents covering our existing compounds, products and processes, and those that we will likely file in the future, may not provide complete or adequate protection. Filing patent applications is a fact-intensive and complex process. We may file patent applications that ultimately do not result in patents or have patents that do not provide adequate protection for the related product. Future litigation or other proceedings regarding the enforcement or validity of our existing patents or any future patents could result in the invalidation of our patents or substantially reduce their protection. In addition, we may face criticism as a result of our legitimate use of the patent systems to protect our investments in new and useful innovations in medicine.

Generic manufacturers have sought, and may continue to seek, FDA approval to market generic versions of our products through an abbreviated new drug application ("ANDA"), the application process typically used by manufacturers seeking approval of a generic drug. For a description of our ANDA litigation, see Note 10. Commitments and Contingencies of the Notes to Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q. ANDA litigation and related settlement and license agreements, in some cases, may result in a loss of exclusivity for our patents sooner than we would otherwise expect. In addition, loss of exclusivity may be earlier than expected under these settlement and license agreements under certain circumstances. For example, settlement and license agreements with generic manufacturers typically include acceleration clauses that permit generic entry before the agreed-upon entry date in certain circumstances, and generic manufacturers may continue to challenge the patents protecting our products. The entry of generic versions of our products has, and may in the future, lead to market share and price erosion.

If we are found to infringe the valid patents of third parties, we may be required to pay significant monetary damages or we may be prevented from commercializing products or may be required to obtain licenses from these third parties. We may not be able to obtain alternative technologies or any required license on commercially reasonable terms or at all. If we fail to obtain these licenses or alternative technologies, we may be unable to develop or commercialize some or all of our products. For example, we are aware of patents and patent applications owned by other parties that such parties may claim to cover the use of our products and research activities. For a description of our pending patent litigation, see Note 10. Commitments and Contingencies of the Notes to Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Furthermore, we also rely on unpatented trade secrets and improvements, unpatented internal know-how and technological innovation. We protect these rights mainly through confidentiality agreements with our corporate partners, employees, consultants and vendors. We cannot be certain that these parties will comply with these confidentiality agreements, that we have adequate remedies for any breach or that our trade secrets, internal know-how or technological innovation will not otherwise become known or be independently discovered by our competitors. Under some of our R&D agreements, inventions become jointly owned by us and our corporate partner and in other cases become the exclusive property of one party. In certain circumstances, it can be difficult to determine who owns a particular invention and disputes could arise regarding those inventions. We could be adversely affected if our trade secrets, internal know-how, technological innovation or confidential information become known or independently discovered by competitors or if we enter into disputes over ownership of inventions.

We face potentially significant liability and increased expenses from litigation and government investigations relating to our products and operations.

We are involved in a number of litigation, investigation and other dispute-related matters that require us to expend substantial internal and financial resources. From time to time, these matters require us to pay significant monetary amounts, including royalty payments for past and future sales. We expect these matters will continue to require a high level of internal and financial resources for the foreseeable future. These matters have reduced, and are expected to continue to reduce, our earnings and require significant management attention.

In addition, the testing, manufacturing, marketing and use of our commercial products, as well as product candidates in development, involve substantial risk of product liability claims. These claims may be made directly by consumers, healthcare providers, pharmaceutical companies or others. We have limited insurance for product liabilities that may arise and claims may exceed our coverage.

For a description of our litigation, investigation and other dispute-related matters, see Note 10. Commitments and Contingencies of the Notes to Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q. The outcome of such legal proceedings or any other legal proceedings that may be brought against us, the investigations or any other investigations that may be initiated and any other dispute-related matters, are inherently uncertain, and adverse developments or outcomes can result in significant expenses, monetary damages, penalties or injunctive relief against us.

Operational Risks

Our business has been, and may in the future be, adversely affected by outbreaks of epidemic, pandemic or contagious diseases.

Actual or threatened outbreaks of epidemic, pandemic or contagious diseases, or other public health emergencies, may significantly disrupt our global operations and adversely affect our business, financial condition and results of operations. As we have seen with the COVID-19 pandemic, outbreaks can result in global supply chain and logistics disruptions and distribution constraints. The impact of an outbreak or other public health crisis on our results of operations and financial condition would depend on numerous evolving factors, but could involve higher operating expenses, lower demand for our products as a result of governmental, business and individuals' actions taken in response to such an event (including quarantines, travel restrictions and interruptions to healthcare services, which can impact enrollment in or operation of our clinical trials or limit patients' ability or willingness to access and seek care), challenges associated with the safety of our employees and safe occupancy of our job sites, and financial market volatility and significant macroeconomic uncertainty in global markets. An outbreak or public health emergency also could amplify many of the other risks described throughout the "Risk Factors" section of this Quarterly Report on Form 10-Q.

We face risks associated with our global operations.

Our global operations are accompanied by certain financial, political, economic and other risks, including those listed below:

- **Foreign Currency Exchange:** For the six months ended June 30, 2023, approximately 28% of our product sales were outside the U.S. Because a significant percentage of our product sales is denominated in foreign currencies, primarily the Euro, we face exposure to adverse movements in foreign currency exchange rates. Overall, we are a net receiver of foreign currencies, and therefore, we benefit from a weaker U.S. dollar and are adversely affected by a stronger U.S. dollar. Our hedging program does not eliminate our exposure to currency fluctuations. We may be adversely impacted if the U.S. dollar appreciates significantly against certain currencies and our hedging program does not sufficiently offset the effects of such appreciation. For example, see “Foreign Currency Exchange Impact” in Part I, Item 2 of this Quarterly Report on Form 10-Q for a discussion of our exposure to movements in foreign currency exchange rates, primarily in the Euro, and the impacts from foreign currency exchange, net of hedges, for the six months ended June 30, 2023.
- **Interest Rates and Inflation:** We hold interest-generating assets and interest-bearing liabilities, including our available-for-sale debt securities and our senior unsecured notes and credit facilities. Fluctuations in interest rates, including the U.S. Federal Reserve’s recent increases in interest rates, could expose us to increased financial risk. In addition, high inflation, such as what we are seeing in the current economic environment, has adversely impacted and may continue to adversely impact our business and financial results.
- **Anti-Bribery:** We are subject to the U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws that govern our international operations with respect to payments to government officials. Our international operations are heavily regulated and require significant interaction with foreign officials. We operate in parts of the world that have experienced governmental corruption to some degree. In certain circumstances, strict compliance with anti-bribery laws may conflict with local customs and practices or may require us to interact with doctors and hospitals, some of which may be state-controlled, in a manner that is different than local custom. It is possible that certain of our practices may be challenged under these laws. In addition, our internal control policies and procedures may not protect us from reckless or criminal acts committed by our employees and agents. Enforcement activities under anti-bribery laws could subject us to administrative and legal proceedings and actions, which could result in civil and criminal sanctions, including monetary penalties and exclusion from healthcare programs.

Other risks inherent in conducting a global business include:

- Restrictive government actions against our intellectual property and other foreign assets such as nationalization, expropriation, the imposition of compulsory licenses or similar actions, including waiver of intellectual property protections.
- Protective economic policies taken by foreign governments, such as trade protection measures and import and export licensing requirements, which may result in the imposition of trade sanctions or similar restrictions by the U.S. or other governments.
- Business interruptions stemming from natural or man-made disasters, such as climate change, earthquakes, hurricanes, flooding, fires, extreme heat, drought or actual or threatened public health emergencies, or efforts taken by third parties to prevent or mitigate such disasters, such as public safety power shutoffs and facility shutdowns, for which we may not have sufficient insurance. For example, our corporate headquarters in Foster City and certain R&D and manufacturing facilities are located in California, a seismically active region. In the event of a major earthquake, we may not carry sufficient earthquake insurance, and significant recovery time could be required to resume operations.
- Political instability or disruption in a geographic region where we operate, regardless of cause, including war, terrorism, social unrest and political changes, including in China, Russia and Ukraine.

Our aspirations, goals and disclosures related to environmental, social and governance (“ESG”) matters expose us to numerous risks, including risks to our reputation and stock price.

Institutional and individual investors are increasingly using ESG screening criteria to determine whether Gilead qualifies for inclusion in their investment portfolios. We are frequently asked by investors and other stakeholders to set ambitious ESG goals and provide new and more robust disclosure on goals, progress toward goals and other matters of interest to ESG stakeholders. In response, we have adapted the tracking and reporting of our corporate responsibility program to various evolving ESG frameworks, and we have established and announced goals and other objectives related to ESG matters. These goal statements reflect our current plans and aspirations and are not guarantees that we will be able to achieve them. Our efforts to accomplish and accurately report on these goals and objectives present numerous operational, reputational, financial, legal and other risks, any of which could have a material negative impact, including on our reputation and stock price.

Our ability to achieve any goal or objective, including with respect to environmental and diversity initiatives, is subject to numerous risks, many of which are outside of our control. Examples of such risks include: (1) the availability and cost of low- or non-carbon-based energy sources and technologies, (2) evolving regulatory requirements affecting ESG standards or disclosures, (3) the availability of suppliers that can meet our sustainability, diversity and other standards, (4) our ability to recruit, develop and retain diverse talent in our labor markets and (5) the impact of our organic growth and acquisitions or dispositions of businesses or operations.

The standards for tracking and reporting on ESG matters are relatively new, have not been harmonized and continue to evolve. Our selection of disclosure frameworks that seek to align with various reporting standards may change from time to time and may result in a lack of consistent or meaningful comparative data from period to period. In addition, regulatory authorities may impose mandatory disclosure requirements with respect to ESG matters. For example, in March 2022, U.S. Securities and Exchange Commission (“SEC”) proposed rule changes that would require companies to make certain climate-related disclosures, including information about climate-related risks, greenhouse gas emissions and certain climate-related financial statement metrics. Our processes and controls may not reflect evolving standards for identifying, measuring and reporting ESG matters, immediately or at all, our interpretation of reporting standards may differ from those of others, and such standards may change over time, any of which could result in significant revisions to our goals or reported progress in achieving such goals. In addition, enhancements to our processes and controls to reflect evolving reporting standards may be costly and require additional resources.

If our ESG practices do not meet evolving investor or other stakeholder expectations and standards, then our reputation, our ability to attract or retain employees and our attractiveness as an investment, business partner or acquirer could be negatively impacted. Similarly, our failure or perceived failure to pursue or fulfill our goals, targets and objectives or to satisfy various reporting standards within the timelines we announce, or at all, could also have similar negative impacts and expose us to government enforcement actions and private litigation.

We depend on relationships with third parties for sales and marketing performance, technology, development, logistics and commercialization of products. Failure to maintain these relationships, poor performance by these companies or disputes with these third parties could negatively impact our business.

We rely on a number of collaborative relationships with third parties for our sales and marketing performance in certain territories. In some countries, we rely on international distributors for sales of certain of our products. Some of these relationships also involve the clinical development of these products by our partners. Reliance on collaborative relationships poses a number of risks, including the risk that:

- we are unable to control the resources our corporate partners devote to our programs or products;
- disputes may arise with respect to the ownership of rights to technology developed with our corporate partners;
- disagreements with our corporate partners could cause delays in, or termination of, the research, development or commercialization of product candidates or result in litigation or arbitration;
- contracts with our corporate partners may fail to provide significant protection or may fail to be effectively enforced if one of these partners fails to perform;
- our corporate partners have considerable discretion in electing whether to pursue the development of any additional products and may pursue alternative technologies or products either on their own or in collaboration with our competitors;
- our corporate partners with marketing rights may choose to pursue competing technologies or to devote fewer resources to the marketing of our products than they do to products of their own development; and
- our distributors and our corporate partners may be unable to pay us.

Given these risks, there is a great deal of uncertainty regarding the success of our current and future collaborative efforts. If these efforts fail, our product development or commercialization of new products could be delayed or revenues from products could decline.

Due to the specialized and technical nature of our business, the failure to attract, develop and retain highly qualified personnel could adversely impact us.

Our future success will depend in large part on our continued ability to attract, develop and retain highly qualified scientific, technical and management personnel, as well as personnel with expertise in clinical testing, governmental regulation and commercialization. Our ability to do so also depends in part on how well we maintain a strong workplace culture that is attractive to employees. In addition, competition for qualified personnel in the biopharmaceutical field is intense, and there is a limited pool of qualified potential employees to recruit. We face competition for personnel from other companies, universities, public and private research institutions, government entities and other organizations. Additionally, changes to U.S. immigration and work authorization laws and regulations could make it more difficult for employees to work in or transfer to one of the jurisdictions in which we operate.

The failure to successfully implement or upgrade enterprise resource planning and other information systems could adversely impact our business and results of operations.

We periodically implement or upgrade new or enhanced enterprise resource planning (“ERP”) and other information systems in order to better manage our business operations, align our global organizations and enable future growth. Implementation or upgrade of new business processes and information systems requires the commitment of significant personnel, training and financial resources, and entails risks to our business operations. If we do not successfully implement ERP and other information systems improvements, or if there are delays or difficulties in implementing these systems, we may not realize anticipated productivity improvements or cost efficiencies, and we may experience operational difficulties and challenges in effectively managing our business, all of which could result in quality issues, reputational harm, lost market and revenue opportunities, and otherwise adversely affect our business, financial condition and results of operations.

For example, we are currently in the process of implementing new ERP and other information systems to help us manage our operations and financial reporting. Costs and risks inherent in this transition may include disruptions to business continuity, difficulty in maintaining effective internal controls, administrative and technical problems, interruptions or delays in sales processes, expenditure overruns and data migration issues. If we do not properly address or mitigate these issues it could result in increased costs and diversion of resources, negatively impacting our operating results and ability to effectively manage our business. Additionally, if we do not effectively implement the ERP system as planned, or the ERP system does not operate as intended, the effectiveness of our internal control over financial reporting could be negatively affected.

Information system service interruptions or breaches, including significant cybersecurity incidents, could give rise to legal liability and regulatory action under data protection and privacy laws and adversely affect our business and operations.

We are dependent upon information technology systems, infrastructure and data, including our Kite Connect platform, which is critical to maintain chain of identity and chain of custody of Yescarta and Tecartus. The multitude and complexity of our computer systems make them inherently vulnerable to service interruption or destruction, including those caused by failures during system upgrades or implementations, user error, network or hardware failure, malicious intrusion and ransomware attack. Likewise, data privacy or cybersecurity incidents or breaches by employees or others can result in the exposure of sensitive data, including our intellectual property or trade secrets or the personal information of our employees, patients, customers or other business partners to unauthorized persons or to the public. If our information systems or third-party information systems on which we rely suffer severe damage, disruption or shutdown, including during upgrades or new implementations, and our business continuity plans do not effectively resolve the issues in a timely manner, we could experience delays in reporting our financial results, and we may lose revenue and profits as a result of our inability to timely manufacture, distribute, invoice and collect payments. Cybersecurity attacks and incidents are increasing in their frequency, sophistication and intensity. Malicious actors seek to steal money, gain unauthorized access to, destroy or manipulate data, and disrupt operations, and some of their attacks may not be recognized or discovered until launched or after initial entry into the environment, such as novel or zero-day attacks that are launched before patches are available and defenses can be readied. Malicious actors are also increasingly developing methods to avoid prevention, detection and alerting capabilities, including employing counter-forensic tactics making response activities more difficult. Such attacks and incidents include, for example, the deployment of harmful malware, ransomware, denial-of-service, social engineering and other means to affect service reliability and operations and threaten data confidentiality, integrity and availability. Our business and technology partners face similar risks and any security breach of their systems could adversely affect our security posture.

Like many companies, we have experienced cybersecurity incidents, including data breaches and service interruptions. When cybersecurity incidents occur, our policy is to respond and address them in accordance with applicable governmental regulations and other legal requirements, including our cybersecurity protocols. There can be no assurance that our efforts in response to cybersecurity incidents, as well as our investments to protect our information technology infrastructure and data, will shield us from significant losses, brand and reputational harm and potential liability or prevent any future interruption or breach of our systems. Such cybersecurity incidents can cause the loss of critical or sensitive information, including personal information, and could give rise to legal liability and regulatory action under data protection and privacy laws.

Regulators globally are also imposing new data privacy and security requirements, including new and greater monetary fines for privacy violations. For example, the General Data Protection Regulation (“GDPR”) established regulations regarding the handling of personal data, and non-compliance with the GDPR may result in monetary penalties of up to four percent of worldwide revenue. In addition, new domestic data privacy and security laws, such as the California Consumer Privacy Act and the California Privacy Rights Act and other laws that have been or may be passed, similarly introduce requirements with respect to personal information, and non-compliance with such laws may result in liability through private actions (subject to statutorily defined damages in the event of certain data breaches) and enforcement. Other changes or new laws or regulations associated with the enhanced protection of personal information, could greatly increase our cost of providing our products and services or even prevent us from offering certain services in jurisdictions in which we operate.

Strategic and Financial Risks

We are subject to risks associated with engaging in business acquisitions, licensing arrangements, collaborations, options, equity investments, asset divestitures and other strategic transactions.

We have engaged in, and may in the future engage in, such transactions as part of our business strategy. We may not identify suitable transactions in the future and, if we do, we may not complete such transactions in a timely manner, on a cost-effective basis, or at all, including the possibility that a governmental entity or regulatory body may delay or refuse to grant approval for the consummation of the transaction. If we are successful in making an acquisition or closing a licensing arrangement or collaboration, the products, intellectual property and technologies that are acquired or licensed may not be successful or may require significantly greater resources and investments than anticipated. As part of our annual impairment testing of our goodwill and other indefinite-lived intangible assets in the fourth quarter, and earlier if impairment indicators exist, as required under U.S. generally accepted accounting principles, we may need to recognize impairment charges related to the products, intellectual property and technologies that are acquired or licensed. For example, as a result of an impairment analysis we conducted following our receipt of data in March 2022 from the Phase 3 TROPiCS-02 study evaluating Trodelvy in patients with hormone receptor-positive, human epidermal growth receptor 2-negative metastatic breast cancer, we recognized a partial in-process research and development impairment charge on our Condensed Consolidated Statements of Income during 2022. For option structured deals, there is no assurance that we will elect to exercise our option right, and it is possible that disagreements, uncertainties or other circumstances may arise, including with respect to whether our option rights have been appropriately triggered, which may hinder our ability to realize the expected benefits. For equity investments in our strategic partners, such as in connection with our collaborations with Arcus Biosciences, Inc. and Galapagos NV, the value of our equity investments may fluctuate and decline in value. If we are not successful in the execution or implementation of these transactions, our financial condition, cash flows and results of operations may be adversely affected, and our stock price could decline.

We have paid substantial amounts of cash and incurred additional debt to finance our strategic transactions. Additional indebtedness and a lower cash balance could result in a downgrade of our credit ratings, limit our ability to borrow additional funds or refinance existing debt on favorable terms, increase our vulnerability to adverse economic or industry conditions, and reduce our financial flexibility to continue with our capital investments, stock repurchases and dividend payments. For example, as a result of the cash used and the debt issued in connection with our acquisition of Immunomedics in 2020, S&P Global Ratings downgraded our credit rating. We may be adversely impacted by any failure to overcome these additional risks.

Changes in our effective income tax rate could reduce our earnings.

We are subject to income taxes in the U.S. and various foreign jurisdictions. Due to economic and political conditions, various countries are actively considering and have made changes to existing tax laws, and we cannot predict the form or timing of such changes. Our effective tax rates are affected by changes in the mix of earnings in countries with differing statutory tax rates, changes in the valuation of deferred tax assets and liabilities, the introduction of new taxes, and changes in tax laws, regulations, administrative practices and interpretations, including in the U.S., Germany and Ireland.

We are also subject to the examination of our tax returns and other tax matters by the U.S. Internal Revenue Service and tax authorities in various foreign jurisdictions. There are differing interpretations of tax laws and regulations and, as a result, significant disputes may arise with these tax authorities involving issues of the timing and amount of deductions and allocations of income among various tax jurisdictions. We may be adversely affected by the resolution of one or more of these exposures in any reporting period.

Item 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**Issuer Purchases of Equity Securities**

In the first quarter of 2020, our Board of Directors authorized a \$5.0 billion stock repurchase program (“2020 Program”), with no fixed expiration. Purchases under the 2020 Program may be made in the open market or in privately negotiated transactions.

The table below summarizes our stock repurchase activity for the three months ended June 30, 2023:

	Total Number of Shares Purchased (in thousands)	Average Price Paid per Share	Total Number of Shares Purchased as Part of a Publicly Announced Program (in thousands)	Maximum Fair Value of Shares that May Yet Be Purchased Under the 2020 Program (in millions)
April 1 - April 30, 2023	607	\$ 83.55	568	\$ 4,426
May 1 - May 31, 2023	754	\$ 78.50	700	\$ 4,371
June 1 - June 30, 2023	935	\$ 77.59	615	\$ 4,324
Total	2,296	(1) \$ 79.46	1,883	(1)

(1) The difference between the total number of shares purchased and the total number of shares purchased as part of a publicly announced program is due to shares of common stock withheld by us from employee restricted stock awards in order to satisfy applicable tax withholding obligations.

Item 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

Item 5. OTHER INFORMATION

None of our directors or officers adopted, modified or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement during the quarter ended June 30, 2023, as such terms are defined under Item 408(a) of Regulation S-K.

Item 6. EXHIBITS

Reference is made to the Exhibit Index included herein.

Exhibit Index

Exhibit Footnote	Exhibit Number	Description of Document
(1)	3.1	<u>Restated Certificate of Incorporation of Registrant</u>
(2)	3.2	<u>Amended and Restated Bylaws of Registrant</u>
	4.1	Reference is made to <u>Exhibit 3.1</u> and <u>Exhibit 3.2</u>
(3)	4.2	<u>Indenture related to Senior Notes, dated as of March 30, 2011, between Registrant and Wells Fargo, National Association, as Trustee</u>
(3)	4.3	<u>First Supplemental Indenture related to Senior Notes, dated as of March 30, 2011, between Registrant and Wells Fargo, National Association, as Trustee (including form of Senior Notes)</u>
(4)	4.4	<u>Second Supplemental Indenture related to Senior Notes, dated as of December 13, 2011, between Registrant and Wells Fargo, National Association, as Trustee (including Form of 2041 Note)</u>
(5)	4.5	<u>Third Supplemental Indenture related to Senior Notes, dated as of March 7, 2014, between Registrant and Wells Fargo, National Association, as Trustee (including Form of 2024 Note and Form of 2044 Note)</u>
(6)	4.6	<u>Fourth Supplemental Indenture related to Senior Notes, dated as of November 17, 2014, between Registrant and Wells Fargo, National Association, as Trustee (including Form of 2025 Note and Form of 2045 Note)</u>
(7)	4.7	<u>Fifth Supplemental Indenture, dated as of September 14, 2015, between Registrant and Wells Fargo Bank, National Association, as Trustee (including Form of 2026 Note, Form of 2035 Note and Form of 2046 Note)</u>
(8)	4.8	<u>Sixth Supplemental Indenture, dated as of September 20, 2016, between Registrant and Wells Fargo Bank, National Association, as Trustee (including Form of 2023 Note, Form of 2027 Note, Form of 2036 Note and Form of 2047 Note)</u>
(9)	4.9	<u>Eighth Supplemental Indenture, dated as of September 30, 2020, between the Registrant and Wells Fargo Bank, National Association, as Trustee (including form of notes)</u>
(10)	4.10	<u>Description of Registrant's Securities</u>
(11)	10.1*	<u>Gilead Sciences, Inc. 2004 Equity Incentive Plan, amended and restated May 10, 2017</u>
(12)	10.2*	<u>Amendment No. 1 to Gilead Sciences, Inc. 2004 Equity Incentive Plan, amended and restated May 10, 2017</u>
(13)	10.3*	<u>Gilead Sciences, Inc. 2022 Equity Incentive Plan</u>
(14)	10.4*	<u>Form of employee stock option agreement under 2004 Equity Incentive Plan (for grants made in 2011 through 2018)</u>
(15)	10.5*	<u>Form of employee stock option agreement under 2004 Equity Incentive Plan (for grants made in 2019)</u>
(16)	10.6*	<u>Form of global employee stock option agreement under 2004 Equity Incentive Plan (4 year vest) (for grants made in 2019)</u>
(17)	10.7*	<u>Form of global employee stock option agreement under 2004 Equity Incentive Plan (4 year vest) (for grants made in 2020)</u>
(18)	10.8*	<u>Form of global employee stock option agreement under 2004 Equity Incentive Plan (4 year vest) (for grants made in 2021)</u>
(19)	10.9*	<u>Form of global employee stock option agreement under 2004 Equity Incentive Plan (4 year vest) (for certain grants made in 2022)</u>
(20)	10.10*	<u>Form of global employee stock option agreement under 2022 Equity Incentive Plan (4 year vest) (for certain grants made in 2022)</u>
(21)	10.11*	<u>Form of global employee stock option agreement under 2022 Equity Incentive Plan (4 year vest) (for certain grants commencing in 2023)</u>
(22)	10.12*	<u>Form of non-employee director stock option agreement under 2004 Equity Incentive Plan (for grants made in 2014 through 2018)</u>
(15)	10.13*	<u>Form of non-employee director stock option agreement under 2004 Equity Incentive Plan (for grants made in 2019)</u>
(23)	10.14*	<u>Form of non-employee director stock option agreement under 2004 Equity Incentive Plan (for grants made in 2020 and 2021)</u>
(20)	10.15*	<u>Form of non-employee director stock option agreement under 2022 Equity Incentive Plan (for grants made in 2022)</u>
	10.16*,**	<u>Form of non-employee director stock option agreement under 2022 Equity Incentive Plan (for grants commencing in 2023)</u>
(17)	10.17*	<u>Form of performance share award agreement - TSR Goals (U.S.) under 2004 Equity Incentive Plan (for grants made in 2020)</u>
(18)	10.18*	<u>Form of performance share award agreement - TSR Goals (U.S.) under 2004 Equity Incentive Plan (for grants made in 2021)</u>
(19)	10.19*	<u>Form of performance share award agreement - TSR Goals (U.S.) under 2004 Equity Incentive Plan (for grants made in 2022)</u>
(21)	10.20*	<u>Form of performance share award agreement - TSR Goals (U.S.) under 2022 Equity Incentive Plan (for grants commencing in 2023)</u>
(17)	10.21*	<u>Form of performance share award agreement - Revenue Goals (U.S.) under 2004 Equity Incentive Plan (for grants made in 2020)</u>
(18)	10.22*	<u>Form of performance share award agreement - Revenue Goals (U.S.) under 2004 Equity Incentive Plan (for grants made in 2021)</u>
(19)	10.23*	<u>Form of performance share award agreement - Revenue Goals (U.S.) under 2004 Equity Incentive Plan (for grants made in 2022)</u>
(21)	10.24*	<u>Form of performance share award agreement - Revenue Goals (U.S.) under 2022 Equity Incentive Plan (for grants commencing in 2023)</u>

(15)	10.25*	<u>Form of employee restricted stock unit issuance agreement under 2004 Equity Incentive Plan (for grants made in 2019)</u>
(16)	10.26*	<u>Form of global employee restricted stock unit issuance agreement under 2004 Equity Incentive Plan (4 year vest) (for grants made in 2019)</u>
(17)	10.27*	<u>Form of global employee restricted stock unit issuance agreement under 2004 Equity Incentive Plan (4 year vest) (for grants made in 2020)</u>
(18)	10.28*	<u>Form of global employee restricted stock unit issuance agreement under 2004 Equity Incentive Plan (4 year vest) (for grants made in 2021)</u>
(19)	10.29*	<u>Form of global employee restricted stock unit issuance agreement under 2004 Equity Incentive Plan (4 year vest) (for certain grants made in 2022)</u>
(20)	10.30*	<u>Form of global employee restricted stock unit agreement under 2022 Equity Incentive Plan (4 year vest) (for certain grants made in 2022)</u>
(21)	10.31*	<u>Form of global employee restricted stock unit agreement under 2022 Equity Incentive Plan (4 year vest) (for grants commencing in 2023)</u>
(23)	10.32*	<u>Form of non-employee director restricted stock unit issuance agreement under 2004 Equity Incentive Plan (for grants made in 2020 and 2021)</u>
(20)	10.33*	<u>Form of non-employee director restricted stock unit agreement under 2022 Equity Incentive Plan (for grants made in 2022)</u>
	10.34*, **	<u>Form of non-employee director restricted stock unit agreement under 2022 Equity Incentive Plan (for grants commencing in 2023)</u>
(24)	10.35*	<u>Gilead Sciences, Inc. Employee Stock Purchase Plan, amended and restated January 25, 2023</u>
(15)	10.36*	<u>Gilead Sciences, Inc. 2005 Deferred Compensation Plan, amended and restated April 19, 2016</u>
(23)	10.37*	<u>Gilead Sciences, Inc. Severance Plan, amended and restated May 5, 2020</u>
(17)	10.38*	<u>Gilead Sciences, Inc. Corporate Annual Incentive Plan, amended and restated January 1, 2020</u>
(25)	10.39*	<u>Offer Letter between Registrant and Daniel O'Day, dated November 30, 2018</u>
(15)	10.40*	<u>Stock option agreement for Daniel O'Day under 2004 Equity Incentive Plan</u>
(15)	10.41*	<u>Form of restricted stock unit issuance agreement for Daniel O'Day (in 2019) under 2004 Equity Incentive Plan</u>
(15)	10.42*	<u>Offer Letter between Registrant and Johanna Mercier, dated May 21, 2019</u>
(17)	10.43*	<u>Global stock option agreement for Johanna Mercier (in 2019) under 2004 Equity Incentive Plan</u>
(17)	10.44*	<u>Global restricted stock unit issuance agreement for Johanna Mercier (in 2019) under 2004 Equity Incentive Plan</u>
(17)	10.45*	<u>Offer Letter between Registrant and Merdad Parsey, dated September 29, 2019</u>
(17)	10.46*	<u>Global stock option agreement for Merdad Parsey (in 2019) under 2004 Equity Incentive Plan</u>
(21)	10.47*	<u>Offer Letter between Registrant and Deborah Telman, dated June 2, 2022</u>
(21)	10.48*	<u>Global stock option agreement for Deborah Telman under 2022 Equity Incentive Plan</u>
(21)	10.49*	<u>Global restricted stock unit issuance agreement for Deborah Telman under 2022 Equity Incentive Plan (3 year vest)</u>
(21)	10.50*	<u>Global restricted stock unit issuance agreement for Deborah Telman under 2022 Equity Incentive Plan (4 year vest)</u>
(26)	10.51*	<u>Form of Indemnity Agreement entered into between Registrant and its directors and executive officers</u>
(26)	10.52*	<u>Form of Employee Proprietary Information and Invention Agreement entered into between Registrant and certain of its officers and key employees</u>
(27)	10.53*	<u>Form of Employee Proprietary Information and Invention Agreement entered into between Registrant and certain of its officers and key employees (revised September 2006)</u>
+(28)	10.54	<u>Amendment Agreement, dated October 25, 1993, between Registrant, the Institute of Organic Chemistry and Biochemistry (IOCB) and Rega Stichting v.z.w. (REGA), together with the following exhibits: the License Agreement, dated December 15, 1991, between Registrant, IOCB and REGA (the 1991 License Agreement); the License Agreement, dated October 15, 1992, between Registrant, IOCB and REGA (the October 1992 License Agreement); and the License Agreement, dated December 1, 1992, between Registrant, IOCB and REGA (the December 1992 License Agreement)</u>
+(29)	10.55	<u>Amendment Agreement between Registrant and IOCB/REGA, dated December 27, 2000, amending the 1991 License Agreement and the December 1992 License Agreement</u>
+(30)	10.56	<u>Sixth Amendment Agreement to the License Agreement, between IOCB/REGA and Registrant, dated August 18, 2006, amending the October 1992 License Agreement and the December 1992 License Agreement</u>
+(31)	10.57	<u>Seventh Amendment Agreement to the License Agreement, between IOCB/REGA and Registrant, dated July 1, 2013, amending the October 1992 License Agreement and the December 1992 License Agreement</u>
+(32)	10.58	<u>Exclusive License Agreement by and between Registrant (as successor to Triangle Pharmaceuticals, Inc.), Glaxo Group Limited, The Wellcome Foundation Limited, Glaxo Wellcome Inc. and Emory University, dated May 6, 1999</u>
+(33)	10.59	<u>Royalty Sale Agreement by and among Registrant, Emory University and Investors Trust & Custodial Services (Ireland) Limited, solely in its capacity as Trustee of Royalty Pharma, dated July 18, 2005</u>
+(33)	10.60	<u>Amended and Restated License Agreement by and between Registrant, Emory University and Investors Trust & Custodial Services (Ireland) Limited, solely in its capacity as Trustee of Royalty Pharma, dated July 21, 2005</u>
++(34)	10.61	<u>Amended and Restated EVG License Agreement by and between Japan Tobacco Inc. and Registrant, dated November 29, 2018</u>

++(34)	10.62	<u>Master Agreement by and between Registrant, Gilead Sciences K.K. and Japan Tobacco Inc., dated November 29, 2018</u>
+(35)	10.63	<u>Amended and Restated Collaboration Agreement by and among Registrant, Gilead Sciences Ireland UC (formerly Gilead Sciences Limited) and Janssen R&D Ireland, dated December 25, 2014</u>
+(36)	10.64	<u>License Agreement by and among Kite Pharma, Inc., Cabaret Biotech Ltd. and Dr. Zelig Eshhar, dated December 12, 2013</u>
++(16)	10.65	<u>Option, License and Collaboration Agreement by and between Galapagos NV and Registrant, dated July 14, 2019</u>
	31.1**	<u>Certification of Chief Executive Officer, as required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended</u>
	31.2**	<u>Certification of Chief Financial Officer, as required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended</u>
	32***	<u>Certifications of Chief Executive Officer and Chief Financial Officer, as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350)</u>
	101.INS**	XBRL Instance Document - The instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
	101.SCH**	Inline XBRL Taxonomy Extension Schema Document
	101.CAL**	Inline XBRL Taxonomy Extension Calculation Linkbase Document
	101.DEF**	Inline XBRL Taxonomy Extension Definition Linkbase Document
	101.LAB**	Inline XBRL Taxonomy Extension Label Linkbase Document
	101.PRE**	Inline XBRL Taxonomy Extension Presentation Linkbase Document
	104	Cover Page Interactive Data File, formatted in Inline XBRL (included as Exhibit 101)

- (1) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on May 9, 2019, and incorporated herein by reference.
- (2) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on February 6, 2023, and incorporated herein by reference.
- (3) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on April 1, 2011, and incorporated herein by reference.
- (4) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on December 13, 2011, and incorporated herein by reference.
- (5) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on March 7, 2014, and incorporated herein by reference.
- (6) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on November 17, 2014, and incorporated herein by reference.
- (7) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on September 14, 2015, and incorporated herein by reference.
- (8) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on September 20, 2016, and incorporated herein by reference.
- (9) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on September 30, 2020, and incorporated herein by reference.
- (10) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2019, and incorporated herein by reference.
- (11) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on May 12, 2017, and incorporated herein by reference.
- (12) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2020, and incorporated herein by reference.
- (13) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on May 5, 2022, and incorporated herein by reference.
- (14) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2011, and incorporated herein by reference.
- (15) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019, and incorporated herein by reference.
- (16) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2019, and incorporated herein by reference.
- (17) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, and incorporated herein by reference.
- (18) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2021, and incorporated herein by reference.
- (19) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, and incorporated herein by reference.
- (20) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, and incorporated herein by reference.
- (21) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, and incorporated herein by reference.
- (22) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2014, and incorporated herein by reference.
- (23) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2020, and incorporated herein by reference.
- (24) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on May 5, 2023, and incorporated herein by reference.
- (25) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on December 10, 2018, and incorporated herein by reference.
- (26) Filed as an exhibit to Registrant's Registration Statement on Form S-1 (No. 33-55680), as amended, and incorporated herein by reference.
- (27) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2006, and incorporated herein by reference.
- (28) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended March 31, 1994, and incorporated herein by reference.
- (29) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2000, and incorporated herein by reference.
- (30) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2006, and incorporated herein by reference.
- (31) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2013, and incorporated herein by reference.
- (32) Filed as an exhibit to Triangle Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q/A filed on November 3, 1999, and incorporated herein by reference.
- (33) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2005, and incorporated herein by reference.
- (34) Filed as an exhibit to Registrant's Amendment No. 1 to Annual Report on Form 10-K/A filed on April 18, 2019, and incorporated herein by reference.
- (35) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2014, and incorporated herein by reference.
- (36) Filed as an exhibit to Kite Pharma, Inc.'s Registration Statement on Form S-1/A (No. 333-196081) filed on June 17, 2014, and incorporated herein by reference.

* Management contract or compensatory plan or arrangement.

** Filed herewith.

*** Furnished herewith.

+ Certain confidential portions of this Exhibit were omitted by means of marking such portions with an asterisk (the Mark). This Exhibit has been filed separately with the Secretary of the Securities and Exchange Commission without the Mark pursuant to Registrant's Application Requesting Confidential Treatment under Rule 24b-2 under the Securities Exchange Act of 1934, as amended.

++ Certain confidential portions of this Exhibit were omitted by means of marking such portions with the Mark because the identified confidential portions are (i) not material and (ii) would be competitively harmful if publicly disclosed.

SIGNATURES

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

GILEAD SCIENCES, INC.
(Registrant)

Date: August 4, 2023

/s/ DANIEL P. O'DAY

Daniel P. O'Day
Chairman and Chief Executive Officer
(Principal Executive Officer)

Date: August 4, 2023

/s/ ANDREW D. DICKINSON

Andrew D. Dickinson
Chief Financial Officer
(Principal Financial Officer)