
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 September 30, 2022

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 October 31, 2022: 1,254,243,845

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[®], 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.

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; statements regarding the anticipated future impact on our business of the coronavirus disease 2019 ("COVID-19") and related public health measures; 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 the 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 in addition to the other information in 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)	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 4,699	\$ 5,338
Short-term marketable debt securities	961	1,182
Accounts receivable, net	4,354	4,493
Inventories	1,463	1,618
Prepaid and other current assets	2,077	2,141
Total current assets	13,554	14,772
Property, plant and equipment, net	5,349	5,121
Long-term marketable debt securities	1,282	1,309
Intangible assets, net	29,440	33,455
Goodwill	8,314	8,332
Other long-term assets	4,618	4,963
Total assets	\$ 62,557	\$ 67,952
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 614	\$ 705
Accrued government and other rebates	3,674	3,244
Accrued and other current liabilities	3,865	6,145
Current portion of long-term debt and other obligations, net	2,270	1,516
Total current liabilities	10,423	11,610
Long-term debt, net	22,953	25,179
Long-term income taxes payable	3,982	4,767
Deferred tax liability	3,036	4,356
Other long-term obligations	1,106	976
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; 1,254 shares issued and outstanding	1	1
Additional paid-in capital	5,226	4,661
Accumulated other comprehensive income	98	83
Retained earnings	15,756	16,324
Total Gilead stockholders' equity	21,081	21,069
Noncontrolling interest	(24)	(5)
Total stockholders' equity	21,057	21,064
Total liabilities and stockholders' equity	\$ 62,557	\$ 67,952

See accompanying notes.

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

(in millions, except per share amounts)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenues:				
Product sales	\$ 6,978	\$ 7,356	\$ 19,650	\$ 19,848
Royalty, contract and other revenues	64	65	242	213
Total revenues	7,042	7,421	19,892	20,061
Costs and expenses:				
Cost of goods sold	1,395	1,223	4,261	3,974
Research and development expenses	1,149	1,101	3,429	3,243
Acquired in-process research and development expenses	448	65	786	270
In-process research and development impairment	—	—	2,700	—
Selling, general and administrative expenses	1,213	1,190	3,653	3,596
Total costs and expenses	4,205	3,579	14,829	11,083
Income from operations	2,837	3,842	5,063	8,978
Interest expense	(229)	(250)	(709)	(763)
Other income (expense), net	(176)	(154)	(571)	(696)
Income before income taxes	2,432	3,438	3,783	7,519
Income tax expense	(646)	(852)	(850)	(1,694)
Net income	1,786	2,586	2,933	5,825
Net loss attributable to noncontrolling interest	3	6	19	18
Net income attributable to Gilead	\$ 1,789	\$ 2,592	\$ 2,952	\$ 5,843
Net income per share attributable to Gilead common stockholders – basic	\$ 1.43	\$ 2.06	\$ 2.35	\$ 4.65
Shares used in per share calculation – basic	1,255	1,256	1,255	1,256
Net income per share attributable to Gilead common stockholders – diluted	\$ 1.42	\$ 2.05	\$ 2.34	\$ 4.63
Shares used in per share calculation – diluted	1,261	1,262	1,261	1,262

See accompanying notes.

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

(in millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Net income	\$ 1,786	\$ 2,586	\$ 2,933	\$ 5,825
Other comprehensive income:				
Net foreign currency translation loss, net of tax	(81)	(20)	(102)	(15)
Available-for-sale debt securities:				
Net unrealized loss, net of tax	(7)	—	(38)	(3)
Reclassifications to net income, net of tax	—	—	1	—
Net change	(7)	—	(37)	(3)
Cash flow hedges:				
Net unrealized gain, net of tax	140	37	254	92
Reclassifications to net income, net of tax	(41)	18	(100)	60
Net change	99	55	154	152
Other comprehensive income	11	35	15	134
Comprehensive income	1,797	2,621	2,948	5,959
Comprehensive loss attributable to noncontrolling interest	3	6	19	18
Comprehensive income attributable to Gilead	<u>\$ 1,800</u>	<u>\$ 2,627</u>	<u>\$ 2,967</u>	<u>\$ 5,977</u>

See accompanying notes.

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

Three Months Ended September 30, 2022

(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 June 30, 2022	1,254	\$ 1	\$ 5,031	\$ 87	\$ 15,117	\$ (21)	\$ 20,215
Net income (loss)	—	—	—	—	1,789	(3)	1,786
Other comprehensive income, net of tax	—	—	—	11	—	—	11
Issuances under employee stock purchase plan	2	—	30	—	—	—	30
Issuances under equity incentive plans	2	—	6	—	—	—	6
Stock-based compensation	—	—	170	—	—	—	170
Repurchases of common stock	(4)	—	(11)	—	(217)	—	(228)
Dividends declared (\$0.73 per share)	—	—	—	—	(933)	—	(933)
Balance as of September 30, 2022	1,254	\$ 1	\$ 5,226	\$ 98	\$ 15,756	\$ (24)	\$ 21,057

Nine Months Ended September 30, 2022

(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 December 31, 2021	1,254	\$ 1	\$ 4,661	\$ 83	\$ 16,324	\$ (5)	\$ 21,064
Net income (loss)	—	—	—	—	2,952	(19)	2,933
Other comprehensive income, net of tax	—	—	—	15	—	—	15
Issuances under employee stock purchase plan	3	—	103	—	—	—	103
Issuances under equity incentive plans	9	—	30	—	—	—	30
Stock-based compensation	—	—	465	—	—	—	465
Repurchases of common stock	(12)	—	(33)	—	(723)	—	(756)
Dividends declared (\$2.19 per share)	—	—	—	—	(2,797)	—	(2,797)
Balance as of September 30, 2022	1,254	\$ 1	\$ 5,226	\$ 98	\$ 15,756	\$ (24)	\$ 21,057

See accompanying notes.

Three Months Ended September 30, 2021

	Nine Months Ended September 30, 2021						
	Gilead Stockholders' Equity						
	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Retained Earnings	Noncontrolling Interest	Total Stockholders' Equity
(in millions, except per share amounts)	Shares	Amount					
Balance as of June 30, 2021	1,254	\$ 1	\$ 4,271	\$ 39	\$ 15,392	\$ 7	\$ 19,710
Net income (loss)	—	—	—	—	2,592	(6)	2,586
Other comprehensive income, net of tax	—	—	—	35	—	—	35
Issuances under employee stock purchase plan	1	—	35	—	—	—	35
Issuances under equity incentive plans	3	—	22	—	—	—	22
Stock-based compensation	—	—	171	—	—	—	171
Repurchases of common stock	(3)	—	(7)	—	(176)	—	(183)
Dividends declared (\$0.71 per share)	—	—	—	—	(905)	—	(905)
Balance as of September 30, 2021	1,255	\$ 1	\$ 4,492	\$ 74	\$ 16,903	\$ 1	\$ 21,471

Nine Months Ended September 30, 2021

	Nine Months Ended September 30, 2021						
	Gilead Stockholders' Equity						
	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Retained Earnings	Noncontrolling Interest	Total Stockholders' Equity
(in millions, except per share amounts)	Shares	Amount					
Balance as of December 31, 2020	1,254	\$ 1	\$ 3,880	\$ (60)	\$ 14,381	\$ 19	\$ 18,221
Net income (loss)	—	—	—	—	5,843	(18)	5,825
Other comprehensive income, net of tax	—	—	—	134	—	—	134
Issuances under employee stock purchase plan	2	—	111	—	—	—	111
Issuances under equity incentive plans	9	—	46	—	—	—	46
Stock-based compensation	—	—	479	—	—	—	479
Repurchases of common stock	(10)	—	(24)	—	(607)	—	(631)
Dividends declared (\$2.13 per share)	—	—	—	—	(2,714)	—	(2,714)
Balance as of September 30, 2021	1,255	\$ 1	\$ 4,492	\$ 74	\$ 16,903	\$ 1	\$ 21,471

See accompanying notes.

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

(in millions)	Nine Months Ended September 30,	
	2022	2021
Operating Activities:		
Net income	\$ 2,933	\$ 5,825
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation expense	240	239
Amortization expense	1,335	1,276
Stock-based compensation expense	463	476
Acquired in-process research and development expenses	786	270
In-process research and development impairment	2,700	—
Deferred income taxes	(1,214)	243
Net loss from equity securities	596	667
Other	546	508
Changes in operating assets and liabilities:		
Accounts receivable, net	(125)	272
Inventories	(34)	(24)
Prepaid expenses and other	12	(17)
Accounts payable	(38)	(242)
Income taxes payable	(564)	(463)
Accrued and other liabilities	(1,131)	(851)
Net cash provided by operating activities	6,505	8,179
Investing Activities:		
Purchases of marketable debt securities	(1,398)	(2,891)
Proceeds from sales of marketable debt securities	370	506
Proceeds from maturities of marketable debt securities	1,232	1,808
Acquisitions, including in-process research and development, net of cash acquired	(1,579)	(1,540)
Purchases of equity securities	(166)	(332)
Capital expenditures	(547)	(423)
Other	(3)	19
Net cash used in investing activities	(2,091)	(2,853)
Financing Activities:		
Proceeds from issuances of common stock	133	157
Repurchases of common stock	(604)	(497)
Repayments of debt and other obligations	(1,500)	(3,750)
Payments of dividends	(2,794)	(2,711)
Other	(150)	(134)
Net cash used in financing activities	(4,915)	(6,935)
Effect of exchange rate changes on cash and cash equivalents	(138)	(26)
Net change in cash and cash equivalents	(639)	(1,635)
Cash and cash equivalents at beginning of period	5,338	5,997
Cash and cash equivalents at end of period	\$ 4,699	\$ 4,362

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, 2021, included in our Annual Report on Form 10-K filed with the 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 except for our classification of expenses related to development milestones and other collaboration payments made prior to regulatory approval of a developed product. Beginning in the second quarter of 2022, we reclassified such expenses from Research and development expenses to Acquired in-process research and development expenses in the Condensed Consolidated Statements of Income. Concurrently, we reclassified the cash payments related to these expenses from Other to Acquisitions, including in-process research and development, net of cash acquired within Investing Activities in the Condensed Consolidated Statements of Cash Flows. We believe this presentation assists users of the financial statements to better understand the total costs incurred to acquire in-process research and development (“IPR&D”) projects. Prior periods have been revised to reflect this classification, resulting in a reduction of previously-reported Research and development expenses of \$46 million and \$93 million for the three and nine months ended September 30, 2021, respectively, and \$8 million for the three months ended March 31, 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 September 30, 2022				Three Months Ended September 30, 2021			
	U.S.	Europe	Other International	Total	U.S.	Europe	Other International	Total
Product sales:								
HIV								
Biktarvy	\$ 2,286	\$ 278	\$ 201	\$ 2,766	\$ 1,875	\$ 254	\$ 147	\$ 2,276
Complera/Eviplera	20	21	3	43	28	31	5	64
Descovy	444	28	28	500	355	42	36	433
Genvoya	502	71	27	600	576	100	68	744
Odefsey	276	86	12	374	275	112	12	399
Stribild	22	7	3	32	28	11	3	42
Truvada	24	3	2	30	55	5	7	67
Revenue share - Symtuza ⁽¹⁾	85	40	4	130	86	41	3	130
Other HIV ⁽²⁾	1	6	5	12	24	6	4	34
Total HIV	3,661	541	285	4,487	3,302	602	285	4,189
Veklury	336	130	458	925	1,527	109	287	1,923
Hepatitis C virus ("HCV")								
Ledipasvir/Sofosbuvir ⁽³⁾	8	5	12	25	14	5	26	45
Sofosbuvir/Velpatasvir ⁽⁴⁾	241	131	84	455	173	77	82	332
Other HCV ⁽⁵⁾	34	7	2	44	37	12	3	52
Total HCV	283	143	98	524	224	94	111	429
Hepatitis B virus ("HBV") / Hepatitis delta virus ("HDV")								
Vemlidy	129	9	90	228	103	9	96	208
Viread	2	5	15	22	1	7	18	26
Other HBV/HDV ⁽⁶⁾	—	13	—	14	—	13	—	13
Total HBV/HDV	131	28	106	264	104	29	114	247
Cell therapy								
Tecartus	60	20	1	81	35	12	—	47
Yescarta	210	91	16	317	100	66	9	175
Total cell therapy	270	111	17	398	135	78	9	222
Trodelvy	139	38	3	180	100	1	—	101
Other								
AmBisome	9	63	33	105	7	67	69	143
Letairis	43	—	—	43	46	—	—	46
Other ⁽⁷⁾	28	11	13	52	34	17	5	56
Total other	80	75	46	200	87	84	74	245
Total product sales	4,900	1,064	1,013	6,978	5,479	997	880	7,356
Royalty, contract and other revenues	28	37	—	64	30	34	1	65
Total revenues	<u>\$ 4,928</u>	<u>\$ 1,101</u>	<u>\$ 1,013</u>	<u>\$ 7,042</u>	<u>\$ 5,509</u>	<u>\$ 1,031</u>	<u>\$ 881</u>	<u>\$ 7,421</u>

(in millions)	Nine Months Ended September 30, 2022				Nine Months Ended September 30, 2021			
	U.S.	Europe	Other International	Total	U.S.	Europe	Other International	Total
Product sales:								
HIV								
Biktarvy	\$ 6,088	\$ 807	\$ 577	\$ 7,472	\$ 4,926	\$ 707	\$ 461	\$ 6,094
Complera/Eviplera	56	76	10	142	73	104	12	189
Descovy	1,152	92	91	1,335	994	128	105	1,227
Genvoya	1,441	220	103	1,764	1,633	306	184	2,123
Odefsey	763	278	36	1,077	773	336	39	1,148
Stribild	68	23	7	98	94	33	12	139
Truvada	77	12	13	102	268	18	24	310
Revenue share - Symtuza ⁽¹⁾	251	126	10	388	261	125	8	394
Other HIV ⁽²⁾	11	20	15	45	110	19	24	153
Total HIV	9,906	1,653	863	12,422	9,132	1,776	869	11,777
Veklury	1,179	560	1,166	2,905	2,763	761	684	4,208
HCV								
Ledipasvir/Sofosbuvir ⁽³⁾	27	13	43	83	63	24	76	163
Sofosbuvir/Velpatasvir ⁽⁴⁾	629	288	244	1,161	649	234	272	1,155
Other HCV ⁽⁵⁾	88	31	7	127	97	64	9	170
Total HCV	745	332	294	1,371	809	322	357	1,488
HBV/HDV								
Vemlidy	306	27	289	622	266	25	298	589
Viread	4	17	48	69	8	22	55	85
Other HBV/HDV ⁽⁶⁾	1	41	—	42	1	29	—	30
Total HBV/HDV	311	85	337	733	275	76	353	704
Cell therapy								
Tecartus	160	56	2	217	94	25	—	119
Yescarta	528	253	42	823	300	188	25	513
Total cell therapy	688	308	44	1,040	394	213	25	632
Trodelyv	379	98	8	485	261	1	—	262
Other								
Ambisome	48	192	140	380	32	202	186	420
Letairis	135	—	—	135	157	—	—	157
Other ⁽⁷⁾	91	52	35	178	109	68	23	200
Total other	275	244	174	693	298	270	209	777
Total product sales	13,482	3,281	2,887	19,650	13,932	3,419	2,497	19,848
Royalty, contract and other revenues	140	98	4	242	70	140	3	213
Total revenues	\$ 13,622	\$ 3,378	\$ 2,891	\$ 19,892	\$ 14,002	\$ 3,559	\$ 2,500	\$ 20,061

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

⁽²⁾ Includes Atripla, Emtriva 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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
AmerisourceBergen Corporation	18 %	25 %	17 %	24 %
Cardinal Health, Inc.	25 %	22 %	25 %	21 %
McKesson Corporation	22 %	21 %	20 %	18 %

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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenue share with Janssen and royalties for licenses of intellectual property	\$ 192	\$ 190	\$ 573	\$ 625
Changes in estimates	\$ 207	\$ 188	\$ 452	\$ 661

Contract Balances

Our contract assets, which consist of unbilled amounts primarily from arrangements where the licensing of intellectual property is the only or predominant performance obligation, totaled \$164 million and \$174 million as of September 30, 2022 and December 31, 2021, respectively. Contract liabilities, which generally result from receipt of advance payment before our performance under the contract, were \$85 million and \$79 million as of September 30, 2022 and December 31, 2021, respectively.

3. FAIR VALUE MEASUREMENTS

We determine the fair value of financial and non-financial assets and liabilities using the fair value hierarchy, which establishes three levels of inputs that may be used to measure fair value, as follows:

- Level 1 inputs include quoted prices in active markets for identical assets or liabilities;
- Level 2 inputs include observable inputs other than Level 1 inputs, such as quoted prices for similar assets or liabilities in active markets; quoted prices for identical or similar assets or liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the asset or liability; and
- Level 3 inputs include unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the underlying asset or liability. Our Level 3 assets and liabilities include those whose fair value measurements are determined using pricing models, discounted cash flow methodologies or similar valuation techniques and significant management judgment or estimation.

Our financial instruments consist primarily of cash and cash equivalents, marketable debt securities, accounts receivable, foreign currency exchange contracts, equity securities, accounts payable and short-term and long-term debt. Cash and cash equivalents, marketable debt securities, certain equity securities and foreign currency exchange contracts are reported at their respective fair values on our Condensed Consolidated Balance Sheets. Equity securities without readily determinable fair values are recorded using the measurement alternative of cost less impairment, if any, adjusted for observable price changes in orderly transactions for identical or similar investments of the same issuer. Short-term and long-term debt are reported at their amortized costs on our Condensed Consolidated Balance Sheets. The remaining financial instruments are reported on our Condensed Consolidated Balance Sheets at amounts that approximate current fair values.

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)	September 30, 2022				December 31, 2021			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Assets:								
Available-for-sale debt securities:								
U.S. treasury securities	\$ 448	\$ —	\$ —	\$ 448	\$ 407	\$ —	\$ —	\$ 407
U.S. government agencies securities	—	19	—	19	—	4	—	4
Non-U.S. government securities	—	44	—	44	—	50	—	50
Certificates of deposit	—	65	—	65	—	249	—	249
Corporate debt securities	—	1,367	—	1,367	—	1,363	—	1,363
Residential mortgage and asset-backed securities	—	347	—	347	—	424	—	424
Equity securities:								
Money market funds	3,316	—	—	3,316	3,661	—	—	3,661
Equity investment in Galapagos NV (“Galapagos”)	703	—	—	703	931	—	—	931
Equity investment in Arcus Biosciences, Inc. (“Arcus”)	361	—	—	361	559	—	—	559
Other publicly traded equity securities	205	—	—	205	331	—	—	331
Deferred compensation plan	208	—	—	208	261	—	—	261
Foreign currency derivative contracts	—	242	—	242	—	80	—	80
Total	\$ 5,242	\$ 2,084	\$ —	\$ 7,325	\$ 6,150	\$ 2,170	\$ —	\$ 8,320
Liabilities:								
Liability for MYR GmbH (“MYR”) contingent consideration	\$ —	\$ —	\$ 249	\$ 249	\$ —	\$ —	\$ 317	\$ 317
Deferred compensation plan	208	—	—	208	261	—	—	261
Foreign currency derivative contracts	—	2	—	2	—	5	—	5
Total	\$ 208	\$ 2	\$ 249	\$ 458	\$ 261	\$ 5	\$ 317	\$ 583

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 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

Substantially all of our foreign currency derivative contracts have maturities within an 18-month time horizon 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 values of our senior unsecured notes, determined using Level 2 inputs based on their quoted market values, were approximately \$21.2 billion and \$28.6 billion as of September 30, 2022 and December 31, 2021, respectively, and the carrying values were \$24.1 billion and \$25.6 billion as of September 30, 2022 and December 31, 2021, respectively.

Level 3 Inputs

Contingent Consideration

In connection with our first quarter 2021 acquisition of MYR, we recorded a liability for contingent consideration, which is revalued each reporting period until the related contingency is resolved. The contingent consideration was estimated using probability-weighted scenarios for U.S. Food and Drug Administration ("FDA") approval of Hepcludex.

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

(in millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Beginning balance	\$ 306	\$ 334	\$ 317	\$ —
Additions	—	—	—	341
Changes in valuation assumptions	(30)	—	(19)	—
Effect of foreign exchange remeasurement	(27)	(7)	(49)	(13)
Ending balance	\$ 249	\$ 328	\$ 249	\$ 328

Changes in valuation assumptions were primarily related to increasing discount rates and updated probability rate estimates. Such changes were included in Research and development expenses on our Condensed Consolidated Statements of Income. Effect of foreign exchange remeasurement was included in Other income (expense), net on our Condensed Consolidated Statements of Income.

Liability Related to the Sale of Future Royalties

We recorded a liability related to the sale of 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 values of the liability related to the sale of future royalties were \$1.1 billion and \$1.3 billion as of September 30, 2022 and December 31, 2021, respectively, and the carrying value was \$1.1 billion as of September 30, 2022 and December 31, 2021. See Note 9. Debt and Credit Facilities for additional information.

Fair Value Level Transfers

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

Nonrecurring Fair Value Measurements

During the nine months ended September 30, 2022, we recorded a partial impairment charge of \$2.7 billion related to certain IPR&D assets. See Note 7. Goodwill and Intangible Assets for additional information.

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)	September 30, 2022				December 31, 2021			
	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	\$ 456	\$ —	\$ (7)	\$ 448	\$ 408	\$ —	\$ (1)	\$ 407
U.S. government agencies securities	19	—	—	19	4	—	—	4
Non-U.S. government securities	44	—	—	44	50	—	—	50
Certificates of deposit	65	—	—	65	249	—	—	249
Corporate debt securities	1,397	—	(30)	1,367	1,365	—	(2)	1,363
Residential mortgage and asset-backed securities	350	—	(3)	347	425	—	(1)	424
Total	\$ 2,331	\$ —	\$ (40)	\$ 2,290	\$ 2,501	\$ —	\$ (4)	\$ 2,497

The aggregate fair value of investments with unrealized losses was \$2.1 billion and \$2.0 billion as of September 30, 2022 and December 31, 2021, respectively. No allowance for credit losses was recognized for investments with unrealized losses as of September 30, 2022, as 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 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.

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

(in millions)	September 30, 2022	December 31, 2021
Cash and cash equivalents	\$ 47	\$ 6
Short-term marketable debt securities	961	1,182
Long-term marketable debt securities	1,282	1,309
Total	<u>\$ 2,290</u>	<u>\$ 2,497</u>

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

(in millions)	September 30, 2022	
	Amortized Cost	Fair Value
Within one year	\$ 1,018	\$ 1,008
After one year through five years	1,298	1,268
After five years through ten years	7	7
After ten years	7	7
Total	<u>\$ 2,331</u>	<u>\$ 2,290</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. 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.

(in millions)	September 30, 2022	December 31, 2021
Cash and cash equivalents	\$ 3,316	\$ 3,661
Prepaid and other current assets	578	885
Other long-term assets	899	1,197
Total	<u>\$ 4,793</u>	<u>\$ 5,743</u>

Other Equity Securities

Equity method investments and other equity investments without readily determinable fair values were \$415 million and \$338 million as of September 30, 2022 and December 31, 2021, respectively, and were included in Other long-term assets on our Condensed Consolidated Balance Sheets.

Unrealized Gains and Losses

Net unrealized losses recognized on equity securities were \$197 million and \$596 million for the three and nine months ended September 30, 2022, and \$142 million and \$667 million for the three and nine months ended September 30, 2021, respectively, and were included in Other income (expense), net on our Condensed Consolidated Statements of Income.

Related Party Transaction

During the nine months ended September 30, 2022 and 2021, 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 and \$212 million was recorded within Selling, general and administrative expenses on our Condensed Consolidated Statements of Income during the nine months ended September 30, 2022 and 2021, respectively.

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 are not designated as hedges and, as a result, changes in their fair value are recorded in Other income (expense), net on our Condensed Consolidated Statements of Income.

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. Upon executing a hedging contract and each reporting period thereafter, we assess hedge effectiveness using regression analysis. The unrealized gains or losses on these hedges are recorded in Accumulated other comprehensive income ("AOCI") and are reclassified into Product sales on our Condensed Consolidated Statements of Income when the respective hedged transactions affect earnings. The majority of gains and losses related to the hedged forecasted transactions reported in AOCI as of September 30, 2022 are expected to be reclassified to Product sales within 12 months.

The cash flow effects of our derivative contracts for the nine months ended September 30, 2022 and 2021 were included within Net cash provided by operating activities on our Condensed Consolidated Statements of Cash Flows.

We had notional amounts of foreign currency exchange contracts outstanding of \$3.0 billion as of September 30, 2022 and \$2.9 billion as of December 31, 2021.

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

(in millions)	September 30, 2022			
	Derivative Assets		Derivative Liabilities	
	Classification	Fair Value	Classification	Fair Value
Derivatives designated as hedges:				
Foreign currency exchange contracts	Prepaid and other current assets	\$ 215	Accrued and other current liabilities	\$ —
Foreign currency exchange contracts	Other long-term assets	17	Other long-term obligations	—
Total derivatives designated as hedges		232		—
Derivatives not designated as hedges:				
Foreign currency exchange contracts	Prepaid and other current assets	10	Accrued and other current liabilities	2
Total derivatives not designated as hedges		10		2
Total derivatives		<u>\$ 242</u>		<u>\$ 2</u>

(in millions)	December 31, 2021			
	Derivative Assets		Derivative Liabilities	
	Classification	Fair Value	Classification	Fair Value
Derivatives designated as hedges:				
Foreign currency exchange contracts	Prepaid and other current assets	\$ 75	Accrued and other current liabilities	\$ 4
Foreign currency exchange contracts	Other long-term assets	5	Other long-term obligations	1
Total derivatives designated as hedges		80		5
Derivatives not designated as hedges:				
Foreign currency exchange contracts	Prepaid and other current assets	—	Accrued and other current liabilities	—
Total derivatives not designated as hedges		—		—
Total derivatives		\$ 80		\$ 5

The following table summarizes the effect of our foreign currency exchange contracts on our Condensed Consolidated Financial Statements:

(in millions)	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2022	2021	2022	2021
Derivatives designated as hedges:				
Gains (losses) recognized in AOCI	\$ 162	\$ 42	\$ 292	\$ 104
Gains (losses) reclassified from AOCI into Product sales	\$ 48	\$ (21)	\$ 115	\$ (69)
Derivatives not designated as hedges:				
Gains (losses) recognized in Other income (expense), net	\$ 6	\$ 5	\$ 70	\$ 24

From time to time, we may discontinue cash flow hedges and, as a result, record related amounts in Other income (expense), net on our Condensed Consolidated Statements of Income. There were no discontinuances of cash flow hedges for the three and nine months ended September 30, 2022 and 2021.

The following table summarizes the potential effect of offsetting our foreign currency exchange contracts on our Condensed Consolidated Balance Sheets:

(in millions)	Gross Amounts of Assets/Liabilities Presented on the Condensed Consolidated Balance Sheets	Gross Amounts Not Offset on the Condensed Consolidated Balance Sheets		
		Derivative Financial Instruments	Cash Collateral Received/Pledged	Net Amount (Legal Offset)
As of September 30, 2022				
Derivative assets	\$ 242	\$ (2)	\$ —	\$ 240
Derivative liabilities	\$ 2	\$ (2)	\$ —	\$ —
As of December 31, 2021				
Derivative assets	\$ 80	\$ (4)	\$ —	\$ 76
Derivative liabilities	\$ 5	\$ (4)	\$ —	\$ 1

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. We also have equity investments in third parties focused on the development and commercialization of products and product candidates.

Acquisitions

MiroBio

On September 20, 2022, we acquired all of the outstanding share capital of MiroBio Ltd. (“MiroBio”), a privately-held U.K.-based biotechnology company focused on restoring immune balance with agonists targeting immune inhibitory receptors, for \$414 million in cash. As a result, MiroBio became our wholly-owned subsidiary.

We accounted for the transaction as an asset acquisition and recorded a \$389 million charge to Acquired in-process research and development expenses on our Condensed Consolidated Statements of Income during the three months ended September 30, 2022. The remaining purchase price relates to various other assets acquired and liabilities assumed.

MYR

In the first quarter of 2021, we completed the acquisition of MYR, a German biotechnology company. MYR focuses on the development and commercialization of therapeutics for the treatment of HDV. The acquisition provided Gilead with Hepcludex, which was conditionally approved by the European Medicines Agency (“EMA”) in July 2020 for the treatment of chronic HDV infection in adults with compensated liver disease. MYR is a wholly-owned subsidiary of Gilead.

The aggregate consideration for this acquisition of €1.3 billion (or \$1.6 billion) primarily consisted of €1.0 billion (or \$1.2 billion) paid upon closing and contingent consideration of up to €300 million, subject to customary adjustments, representing a potential future milestone payment upon FDA approval of Hepcludex. The fair value of this contingent liability, estimated using probability-weighted scenarios for FDA approval, was \$341 million as of the acquisition date. The fair value of this contingent liability was \$249 million as of September 30, 2022 and recorded in Other long-term obligations in our Condensed Consolidated Balance Sheets. See Note 3. Fair Value Measurements for additional information.

The acquisition of MYR was accounted for as a business combination using the acquisition method of accounting. The one-year measurement period was completed in the first quarter of 2022, with adjustments recorded to the fair values of assets acquired and liabilities assumed of \$18 million. See Note 7. Goodwill and Intangible Assets for additional information.

Collaborations and Other Arrangements

Dragonfly

In April 2022, we entered into a strategic research collaboration agreement (the “Dragonfly Collaboration Agreement”) with Dragonfly Therapeutics, Inc. (“Dragonfly”) to develop natural killer (“NK”) cell engager-based immunotherapies for oncology and inflammation indications. Under the terms of the Dragonfly Collaboration Agreement, we received an exclusive, worldwide license from Dragonfly for the 5T4-targeting investigational immunotherapy program, DF7001, as well as options, after the completion of certain preclinical activities, to license exclusive, worldwide rights to develop and commercialize additional NK cell engager programs using the Dragonfly Tri-specific NK Engager platform. Upon the closing of the Dragonfly Collaboration Agreement, we made a \$300 million upfront payment to Dragonfly, and we made an additional \$15 million payment related to a target selection in connection with an August 2022 amendment to the agreement, which were recorded in Acquired in-process research and development expenses on our Condensed Consolidated Statements of Income during the nine months ended September 30, 2022. These payments were classified as Acquisitions, including in-process research and development, net of cash acquired in Investing Activities on our Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2022. In addition, Dragonfly is eligible to receive performance-based development and regulatory milestone payments of up to \$630 million related to the DF7001 program with further commercial milestone payments and royalties on worldwide net sales if certain products are successfully developed and approved. If we exercise our options on additional NK cell engager programs, Dragonfly would be eligible to receive opt-in payments and performance-based development, regulatory and commercial milestone payments and royalties on worldwide net sales on these optioned programs as well.

In 2020, we entered into an option, license and collaboration agreement with Arcus (the “Arcus Collaboration Agreement”), which granted us the right to opt in to all current and future clinical-stage product candidates for up to ten years following the closing of the transaction. In November 2021, we exercised our options to three of the clinical-stage programs and amended the Arcus Collaboration Agreement. The option exercise and amendment transaction closed in December 2021, triggering collaboration opt-in payments of \$725 million and waiving a \$100 million option continuation payment which would have been due to Arcus in the third quarter of 2022. The collaboration opt-in payments of \$725 million were recorded in Accrued and other current liabilities on our Consolidated Balance Sheets as of December 31, 2021 and paid to Arcus in January 2022. Our payments to Arcus were included in Acquisitions, including in-process research and development, net of cash acquired in Investing Activities on our Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2022.

7. GOODWILL AND INTANGIBLE ASSETS

Goodwill

The following table summarizes the changes in the carrying amount of Goodwill:

(in millions)	Amount
Balance as of December 31, 2021	\$ 8,332
Measurement period adjustments	(18)
Balance as of September 30, 2022	<u>\$ 8,314</u>

During the nine months ended September 30, 2022, goodwill decreased by \$18 million as a result of finalizing the amount of acquired net operating losses of MYR, which resulted in a decrease to the net deferred tax liability acquired.

Intangible Assets

The following table summarizes our Intangible assets, net:

(in millions)	September 30, 2022				December 31, 2021			
	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	\$ (6,176)	\$ —	\$ 4,544	\$ 10,720	\$ (5,651)	\$ —	\$ 5,069
Intangible asset – axicabtagene ciloleucel	7,110	(1,806)	—	5,304	7,110	(1,501)	—	5,609
Intangible asset – Trodelvy	5,630	(856)	—	4,774	5,630	(507)	—	5,123
Intangible asset – Hepcludex	845	(136)	—	709	845	(72)	—	773
Other	1,614	(726)	1	889	1,610	(650)	1	961
Total finite-lived assets	25,919	(9,700)	1	16,220	25,915	(8,381)	1	17,535
Indefinite-lived assets – IPR&D	13,220	—	—	13,220	15,920	—	—	15,920
Total intangible assets	<u>\$ 39,139</u>	<u>\$ (9,700)</u>	<u>\$ 1</u>	<u>\$ 29,440</u>	<u>\$ 41,835</u>	<u>\$ (8,381)</u>	<u>\$ 1</u>	<u>\$ 33,455</u>

Aggregate amortization expense related to finite-lived intangible assets was \$445 million and \$1.3 billion for the three and nine months ended September 30, 2022, respectively, and \$441 million and \$1.3 billion for the three and nine months ended September 30, 2021, 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 September 30, 2022:

(in millions)	Amount
2022 (remaining three months)	\$ 445
2023	1,781
2024	1,781
2025	1,776
2026	1,768
Thereafter	8,669
Total	<u>\$ 16,220</u>

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-”) metastatic 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. 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. No other indicators of impairment were noted for both the three and nine months ended September 30, 2022 and 2021.

8. OTHER FINANCIAL INFORMATION

Accounts receivable, net

The following table summarizes our Accounts receivable, net:

(in millions)	September 30, 2022	December 31, 2021
Accounts receivable	\$ 5,006	\$ 5,278
Less: chargebacks	514	671
Less: cash discounts and other	86	67
Less: allowances for credit losses	51	47
Accounts receivable, net	<u>\$ 4,354</u>	<u>\$ 4,493</u>

Inventories

The following table summarizes our Inventories:

(in millions)	September 30, 2022	December 31, 2021
Raw materials	\$ 1,133	\$ 1,112
Work in process	430	590
Finished goods	1,039	1,032
Total	<u>\$ 2,602</u>	<u>\$ 2,734</u>
Reported as:		
Inventories	\$ 1,463	\$ 1,618
Other long-term assets ⁽¹⁾	1,138	1,116
Total	<u>\$ 2,602</u>	<u>\$ 2,734</u>

⁽¹⁾ Amounts primarily consist of raw materials.

Accrued and other current liabilities

The following table summarizes the components of Accrued and other current liabilities:

(in millions)	September 30, 2022	December 31, 2021
Compensation and employee benefits	\$ 752	\$ 927
Income taxes payable	902	539
Allowance for sales returns	392	499
Accrual for settlement related to bictegravir litigation ⁽¹⁾	—	1,250
Other accrued liabilities	1,819	2,930
Total	<u>\$ 3,865</u>	<u>\$ 6,145</u>

⁽¹⁾ See Note 10. Commitments and Contingencies for additional information.

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	September 30, 2022	December 31, 2021
Senior Unsecured	September 2016	March 2022	1.95%	\$ —	\$ 500
Senior Unsecured	September 2015	September 2022	3.25%	—	999
Senior Unsecured	September 2016	September 2023	2.50%	749	748
Senior Unsecured	September 2020	September 2023	0.75%	1,498	1,496
Senior Unsecured	March 2014	April 2024	3.70%	1,748	1,747
Senior Unsecured	November 2014	February 2025	3.50%	1,748	1,747
Senior Unsecured	September 2015	March 2026	3.65%	2,741	2,739
Senior Unsecured	September 2016	March 2027	2.95%	1,247	1,247
Senior Unsecured	September 2020	October 2027	1.20%	747	746
Senior Unsecured	September 2020	October 2030	1.65%	993	993
Senior Unsecured	September 2015	September 2035	4.60%	992	992
Senior Unsecured	September 2016	September 2036	4.00%	742	742
Senior Unsecured	September 2020	October 2040	2.60%	987	987
Senior Unsecured	December 2011	December 2041	5.65%	996	996
Senior Unsecured	March 2014	April 2044	4.80%	1,736	1,736
Senior Unsecured	November 2014	February 2045	4.50%	1,733	1,733
Senior Unsecured	September 2015	March 2046	4.75%	2,221	2,220
Senior Unsecured	September 2016	March 2047	4.15%	1,728	1,727
Senior Unsecured	September 2020	October 2050	2.80%	1,477	1,476
Total senior unsecured notes				24,084	25,571
Liability related to the sale of future royalties				1,139	1,124
Total debt, net				25,223	26,695
Less: Current portion of long-term debt and other obligations, net				2,270	1,516
Total Long-term debt, net				\$ 22,953	\$ 25,179

Senior Unsecured Notes

In February 2022, we repaid \$500 million of senior unsecured notes prior to the March 2022 maturity by exercising a par call option. Additionally, in July 2022, we repaid \$1.0 billion of senior unsecured notes prior to the September 2022 maturity by exercising a par call option. No new debt was issued during the three and nine months ended September 30, 2022. We are required to comply with certain covenants under our note indentures governing our senior unsecured notes. As of September 30, 2022, we were not in violation of any covenants.

Revolving Credit Facility

As of September 30, 2022 and December 31, 2021, 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.

We did not have any material accruals for the matters described below as of September 30, 2022. As of December 31, 2021, we recorded an accrual of \$1.25 billion in Accrued and other current liabilities on our Consolidated Balance Sheets for the previously disclosed legal settlement related to the bictegravir litigation, which we paid in February 2022.

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, now known commercially as 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. The litigation in the U.S. District Court will remain stayed through the appeal proceedings.

Litigation with NuCana plc. (“NuCana”)

NuCana has obtained European Patent No. 2,955,190 (the “EP ’190 patent”) that allegedly covers sofosbuvir. In opposition proceedings before the European Patent Office (“EPO”) held in February 2021, the EPO Opposition Division upheld the validity of the EP ’190 patent in amended form. The EPO has now scheduled the appeal hearing for December 2023. We continue to believe that the amended EP ’190 patent claims are invalid. Subsequent to the EPO opposition decision, we initiated proceedings to invalidate the U.K. counterpart of the EP ’190 patent in the High Court of England & Wales. In March 2021, NuCana filed a counterclaim against us in the High Court of England & Wales alleging patent infringement of the U.K. counterpart and seeking damages and other relief. The hearing date for the U.K. NuCana case has been scheduled for January 2023.

In April 2021, NuCana also filed a lawsuit against us in Germany at the Landgericht Düsseldorf alleging patent infringement of the German counterpart of the EP ’190 patent and seeking damages and injunctive relief. In April 2022, we filed an action for grant of a compulsory license before the Federal Patent Court in Germany. In July 2022, the Düsseldorf court determined that NuCana’s German counterpart of the EP ’190 patent is infringing and granted an injunction. In August 2022, Gilead filed a notice of appeal regarding the Düsseldorf court’s decision.

Litigation Related to Axicabtagene Ciloleucel

In October 2017, Juno Therapeutics, Inc. and Sloan Kettering Cancer Center (collectively, “Juno”) filed a lawsuit against us in the U.S. District Court for the Central District of California, alleging that the commercialization of axicabtagene ciloleucel, sold commercially as Yescarta, infringes U.S. Patent No. 7,446,190 (the “’190 patent”). A jury trial was held on the ’190 patent, and in December 2019, the jury found that the asserted claims of the ’190 patent were valid, and that we willfully infringed the asserted claims of the ’190 patent. The jury also awarded Juno damages in amounts of \$585 million in an upfront payment and a 27.6% running royalty from October 2017 through the date of the jury’s verdict. The parties filed post-trial motions in the first quarter of 2020, and the trial judge entered a judgment in April 2020. The trial judge affirmed the jury’s verdict, enhanced the past damages by 50% and maintained the royalties on future Yescarta sales at 27.6%. In April 2020, we filed an appeal seeking to reverse the judgment or obtain a new trial due to errors made by the trial judge, and in July 2021, the appeals court heard oral arguments. In August 2021, the Court of Appeals for the Federal Circuit (the “CAFC”) reversed the jury verdict, finding the asserted claims of Juno’s patent invalid. In October 2021, Juno filed a petition for rehearing with the CAFC. In January 2022, the CAFC denied Juno’s petition for rehearing. In June 2022, Juno filed a petition for certiorari seeking a review by the Supreme Court. The Supreme Court has not yet ruled on Juno’s petition. We believe that the likelihood of a material adverse outcome in this matter is remote.

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 emtricitabine and tenofovir disoproxil fumarate (“TDF”) or tenofovir alafenamide (“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 breach of contract lawsuit against the U.S. federal government in the U.S. Court of Federal Claims, alleging violations of four material transfer agreements (“MTAs”) related to the research underlying the HHS Patents and a clinical trial agreement (“CTA”) by the U.S. Centers for Disease Control and Prevention related to PrEP research. Although we cannot predict with certainty the ultimate outcome of these litigation matters, we believe that the U.S. federal government breached the MTAs and CTA, 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 trial for the bifurcated portion of the lawsuit in the Court of Federal Claims was held in June 2022, post-trial briefing is now complete, and a decision is not expected until after closing arguments, which were held in October 2022. A trial date for the lawsuit in the Delaware District Court has been set for May 2023.

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 product 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.

Starting in December 2019, we received letters from Lupin Ltd. (“Lupin”), Apotex Inc., Shilpa Medicare Ltd. (“Shilpa”), Sunshine Lake Pharma Co. Ltd. (“Sunshine Lake”), Laurus Labs (“Laurus”), Natco Pharma Ltd. (“Natco”), Macleods Pharma Ltd. (“Macleods”), Hetero Labs Ltd. (“Hetero”) and Cipla Ltd. (“Cipla”) (collectively, “Generic Manufacturers”) indicating that they have submitted ANDAs to FDA requesting permission to market and manufacture generic versions of certain of our TAF-containing products. Between them, these Generic Manufacturers seek to market generic versions of Odefsey, Descovy and Vemlidy. The Generic Manufacturers have challenged the validity of two to four patents listed on the Orange Book and associated with TAF. We filed lawsuits against the Generic Manufacturers, and we intend to enforce and defend our intellectual property. In November 2021, we reached an agreement with Shilpa to resolve the lawsuit against Shilpa; in January 2022, we reached an agreement with Sunshine Lake to resolve the lawsuit against Sunshine Lake; and in May 2022, we reached an agreement with Natco to resolve the lawsuit against Natco. The settlement agreements have been filed with the U.S. Federal Trade Commission and the U.S. Department of Justice as required by law. In April 2022, the case against Laurus was dismissed after Laurus agreed not to challenge any of the Orange Book-listed patents associated with TAF.

In September 2022, we entered into settlement agreements with Lupin, Macleods, Hetero, Apotex Inc., and Cipla to resolve the litigation and patent challenges associated with Descovy, Vemlidy, and Odefsey in the U.S. District Court for the District of Delaware. Pursuant to the settlement agreements, the manufacturers were granted a non-exclusive license in the United States to our patents on tenofovir alafenamide relating to Descovy and Vemlidy beginning on October 31, 2031, and to Odefsey beginning on January 31, 2032, or earlier in certain circumstances. The settlement agreements have been filed with the U.S. Federal Trade Commission and the U.S. Department of Justice as required by law.

In October 2021, we received a letter from 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 Products, L.P. and Janssen (“Janssen”), filed a patent infringement lawsuit against Lupin as co-plaintiffs in the U.S. District Court of Delaware. We separately filed an additional lawsuit against Lupin asserting infringement of two additional patents in the same court. This second case has been stayed pending resolution of the generic litigation regarding our TAF-containing products. Trial has been scheduled for October 2023. 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, filed a patent infringement lawsuit against Apotex as co-plaintiffs in the U.S. District Court of Delaware. 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 and 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.

European Patent Claims

In 2015, several parties filed oppositions in the 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. An appeal hearing has been scheduled for November 2022.

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.

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 hearing for the appeal has been scheduled for March 2023.

The appeal process may take several years for all EPO opposition proceedings. 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, TAF and TAF hemifumarate 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 any of these compounds, 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”) and Johnson & Johnson, Inc., 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 two nationwide classes—one of direct purchasers consisting largely of wholesalers, and another of 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 filed separate lawsuits effectively opting out of the class action cases, asserting claims that are substantively the same as the putative classes. These cases have been coordinated with the class actions. Trial has been set for March 2023.

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 26,000 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 January 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 relator 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. In September 2021, the Texas Court of Appeals for the Sixth Court Appeals District granted our request to stay the Texas litigation pending final judgment in the Eastern District of Pennsylvania lawsuit filed in March 2017, as discussed above.

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. 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. The consolidated lawsuit is pending in the U.S. District Court for the District of New Jersey. In June 2022, plaintiffs filed their Motion for Class Certification, and Immunomedics submitted its Opposition in July 2022. A decision on class certification is pending. While we believe this case is without merit, we cannot predict the ultimate outcome. If plaintiffs are successful in their claims, we could be required to pay significant monetary damages.

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. STOCKHOLDERS' EQUITY

Stock Repurchase Programs

In the first quarter of 2016, our Board of Directors authorized a \$12.0 billion stock repurchase program ("2016 Program") under which repurchases may be made in the open market or in privately negotiated transactions. We started repurchases under the 2016 Program in April 2016.

In the first quarter of 2020, our Board of Directors authorized a \$5.0 billion stock repurchase program ("2020 Program"), which will commence upon the completion of the 2016 Program. Purchases under the 2020 Program may be made in the open market or in privately negotiated transactions.

As of September 30, 2022, the aggregate remaining authorized repurchase amount under both programs was \$5.7 billion.

The following table summarizes our stock repurchases through open market transactions under the 2016 Program:

(in millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Shares repurchased and retired	2.9	2.1	9.5	7.5
Amount	\$ 180	\$ 145	\$ 604	\$ 497

Accumulated Other Comprehensive Income

The following table summarizes the changes in AOCI by component, net of tax:

(in millions)	Foreign Currency Translation, Net of Tax	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)	(102)	(38)	254	114
Reclassifications to net income	—	1	(100)	(99)
Net current period other comprehensive income (loss)	(102)	(37)	154	15
Balance as of September 30, 2022	\$ (89)	\$ (41)	\$ 228	\$ 98

(in millions)	Foreign Currency Translation, Net of Tax	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, 2020	\$ 51	\$ 2	\$ (113)	\$ (60)
Net unrealized gain (loss)	(15)	(3)	92	74
Reclassifications to net income	—	—	60	60
Net current period other comprehensive income (loss)	(15)	(3)	152	134
Balance as of September 30, 2021	\$ 36	\$ (1)	\$ 39	\$ 74

The amounts reclassified to Net income for gains and losses on cash flow hedges are recorded as part of Product sales on our Condensed Consolidated Statements of Income. See Note 5. Derivative Financial Instruments for additional information. The amounts reclassified to Net income for gains and losses on available-for-sale debt securities are recorded as part of Other income (expense), net on our Condensed Consolidated Statements of Income.

12. NET INCOME PER SHARE ATTRIBUTABLE TO GILEAD COMMON STOCKHOLDERS

Basic net income per share attributable to Gilead common stockholders is calculated based on the weighted-average number of shares of our common stock outstanding during the period. Diluted net income per share attributable to Gilead common stockholders is calculated based on the weighted-average number of shares of our common stock and other dilutive securities outstanding during the period. The potentially dilutive shares of our common stock resulting from the assumed exercise of outstanding stock options and equivalents were determined under the treasury stock method.

The following table shows the calculation of basic and diluted net income per share attributable to Gilead common stockholders:

(in millions, except per share amounts)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Net income attributable to Gilead	\$ 1,789	\$ 2,592	\$ 2,952	\$ 5,843
Shares used in per share calculation - basic	1,255	1,256	1,255	1,256
Dilutive effect of stock options and equivalents	6	6	5	6
Shares used in per share calculation - diluted	1,261	1,262	1,261	1,262
Net income per share attributable to Gilead common stockholders - basic	\$ 1.43	\$ 2.06	\$ 2.35	\$ 4.65
Net income per share attributable to Gilead common stockholders - diluted	\$ 1.42	\$ 2.05	\$ 2.34	\$ 4.63

Potential shares of common stock excluded from the computation of diluted net income per share attributable to Gilead common stockholders because their effect would have been antidilutive were 17 million for both the three and nine months ended September 30, 2022, and 14 million and 15 million for the three and nine months ended September 30, 2021, respectively.

13. INCOME TAXES

The following table summarizes our Income tax expense:

(in millions, except percentages)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Income before income taxes	\$ 2,432	\$ 3,438	\$ 3,783	\$ 7,519
Income tax expense	\$ (646)	\$ (852)	\$ (850)	\$ (1,694)
Effective tax rate	26.6 %	24.8 %	22.5 %	22.5 %

Our effective income tax rate of 26.6% and 22.5% for the three and nine months ended September 30, 2022, respectively, was higher than the U.S. federal statutory rate of 21% primarily due to \$389 million of non-deductible Acquired in-process research and development expenses recorded in connection with our acquisition of MiroBio.

Our effective income tax rate of 24.8% for the three months ended September 30, 2021 was higher than the U.S. federal statutory rate of 21% primarily due to remeasurement of certain deferred tax liabilities related to acquired intangible assets, partially offset by provision to return adjustments.

Our effective income tax rate of 22.5% for the nine months ended September 30, 2021 was 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 unfavorable changes in the fair value of our equity investment in Galapagos that are non-deductible for income tax purposes, partially offset by provision to return adjustments.

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 and Irish tax authorities 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.

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 related notes thereto included as part of our Annual Report on Form 10-K for the year ended December 31, 2021 and our unaudited Condensed Consolidated Financial Statements for the three and nine months ended September 30, 2022 and related notes thereto (including Note 1. Organization and Summary of Significant Accounting Policies and Note 6. Acquisitions, Collaborations and Other Arrangements) and other disclosures (including 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. Certain amounts and percentages herein may not sum or recalculate due to rounding.

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 and cancer. We operate in more than 35 countries worldwide, with headquarters in Foster City, California.

Key Business Updates⁽¹⁾

Virology

- In October 2022, we announced that Merck & Co., Inc. ("Merck") and Gilead plan to resume their Phase 2 study under an amended protocol. The study will evaluate an investigational once-weekly oral combination treatment regimen of Merck's islatravir at a lower weekly dose and Gilead's lenacapavir.
- In August 2022, we announced that European Commission ("EC") has granted Marketing Authorization for Sunlenca (lenacapavir) for the treatment of HIV infection, in combination with other antiretroviral(s), in adults with multi-drug resistant HIV infection for whom it is otherwise not possible to construct a suppressive antiviral regimen.

Oncology

- In October 2022, we received European Marketing Authorization for Yescarta use in adults with second-line diffuse large B-cell lymphoma and high-grade B-cell lymphoma ("LBCL"). Additionally, EC granted Marketing Authorization for Tecartus for the treatment of adult relapsed or refractory ("r/r") B-cell precursor acute lymphoblastic leukemia ("ALL"), and in Canada, we received conditional marketing authorization for Yescarta for r/r follicular lymphoma after two or more lines of systemic therapy.
- In October 2022, we announced a strategic collaboration with MacroGenics, Inc. ("MacroGenics") to develop bispecific antibodies to treat various cancers. The agreement includes an upfront payment by us of \$60 million to MacroGenics and an exclusive option granted to us on MGD024, an investigational CD123 and CD3 bispecific.
- In October 2022, we announced that U.S. Food and Drug Administration ("FDA") accepted for Priority Review the supplemental Biologics License Application of Trodelvy for the treatment of patients with pre-treated hormone receptor-positive, human epidermal growth factor receptor 2-negative ("HR+/HER2-") metastatic breast cancer. Trodelvy has not been approved by any regulatory agency for the treatment of HR+/HER2- metastatic breast cancer, and its safety and efficacy have not been established for this indication.
- In August 2022, we announced an agreement to acquire the remaining worldwide development and commercialization rights to Trodelvy from Everest Medicines in Greater China, South Korea, and other Asian markets.

Inflammation

- In September 2022, we completed the acquisition of MiroBio Ltd. ("MiroBio") for \$414 million in cash. MiroBio is a U.K.-based biotechnology company focused on restoring immune balance with agonists targeting immune inhibitory receptors.

⁽¹⁾ 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.

Quarterly Financial Highlights

(in millions, except percentages and per share amounts)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2022	2021	Change	2022	2021	Change
Total revenues	\$ 7,042	\$ 7,421	(5) %	\$ 19,892	\$ 20,061	(1) %
Net income attributable to Gilead	\$ 1,789	\$ 2,592	(31) %	\$ 2,952	\$ 5,843	(49) %
Net income per share attributable to Gilead common stockholders – diluted	\$ 1.42	\$ 2.05	(31) %	\$ 2.34	\$ 4.63	(49) %

Total revenues decreased by 5% and 1% to \$7.0 billion and \$19.9 billion for the three and nine months ended September 30, 2022, respectively, compared to the same periods in 2021, primarily due to lower sales of Veklury, partially offset by higher product sales in HIV, cell therapy and Trodelvy.

Net income attributable to Gilead was \$1.8 billion, or \$1.42 diluted earnings per share, for the three months ended September 30, 2022, compared to \$2.6 billion, or \$2.05 diluted earnings per share for the same period in 2021. The decrease was primarily due to a charge of \$389 million related to our acquisition of MiroBio, lower product sales and higher costs of goods sold, partially offset by lower income tax expense.

Net income attributable to Gilead was \$3.0 billion, or \$2.34 diluted earnings per share, for the nine months ended September 30, 2022, compared to \$5.8 billion, or \$4.63 diluted earnings per share for the same period in 2021. The decrease was primarily due to a partial in-process research and development (“IPR&D”) impairment charge of \$2.7 billion during the three months ended March 31, 2022 related to assets we acquired from Immunomedics, Inc. (“Immunomedics”) in 2020, a charge of \$389 million related to our acquisition of MiroBio, higher costs of goods sold and lower product sales, partially offset by lower income tax expense.

RESULTS OF OPERATIONS

Revenues

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

(in millions, except percentages)	Three Months Ended September 30, 2022				Three Months Ended September 30, 2021				Change
	U.S.	Europe	Other International	Total	U.S.	Europe	Other International	Total	
Product sales:									
HIV	\$ 3,661	\$ 541	\$ 285	\$ 4,487	\$ 3,302	\$ 602	\$ 285	\$ 4,189	7 %
Veklury	336	130	458	925	1,527	109	287	1,923	(52) %
Chronic hepatitis C virus (“HCV”)	283	143	98	524	224	94	111	429	22 %
Chronic hepatitis B virus (“HBV”) / hepatitis delta virus (“HDV”)	131	28	106	264	104	29	114	247	7 %
Cell therapy	270	111	17	398	135	78	9	222	79 %
Trodelvy	139	38	3	180	100	1	—	101	78 %
Other	80	75	46	200	87	84	74	245	(18) %
Total product sales	4,900	1,064	1,013	6,978	5,479	997	880	7,356	(5) %
Royalty, contract and other revenues	28	37	—	64	30	34	1	65	(1) %
Total revenues	\$ 4,928	\$ 1,101	\$ 1,013	\$ 7,042	\$ 5,509	\$ 1,031	\$ 881	\$ 7,421	(5) %

(in millions, except percentages)	Nine Months Ended September 30, 2022				Nine Months Ended September 30, 2021				Change
	U.S.	Europe	Other International	Total	U.S.	Europe	Other International	Total	
Product sales:									
HIV	\$ 9,906	\$ 1,653	\$ 863	\$ 12,422	\$ 9,132	\$ 1,776	\$ 869	\$ 11,777	5 %
Veklury	1,179	560	1,166	2,905	2,763	761	684	4,208	(31) %
HCV	745	332	294	1,371	809	322	357	1,488	(8) %
HBV/HDV	311	85	337	733	275	76	353	704	4 %
Cell therapy	688	308	44	1,040	394	213	25	632	65 %
Trodelvy	379	98	8	485	261	1	—	262	85 %
Other	275	244	174	693	298	270	209	777	(11) %
Total product sales	13,482	3,281	2,887	19,650	13,932	3,419	2,497	19,848	(1) %
Royalty, contract and other revenues	140	98	4	242	70	140	3	213	14 %
Total revenues	\$ 13,622	\$ 3,378	\$ 2,891	\$ 19,892	\$ 14,002	\$ 3,559	\$ 2,500	\$ 20,061	(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 7% and 5% to \$4.5 billion and \$12.4 billion for the three and nine months ended September 30, 2022, respectively, compared to the same periods in 2021, primarily due to changes in product and channel mix leading to higher average realized price and continued higher demand for Biktarvy worldwide, partially offset by lower demand for Truvada driven by the loss of exclusivity in the U.S., and for Genvoya, primarily due to patients switching to Biktarvy.

Veklury

Veklury product sales decreased by 52% and 31% to \$925 million and \$2.9 billion for the three and nine months ended September 30, 2022, respectively, compared to the same periods in 2021, primarily due to lower demand driven by reduced hospitalization rates in the U.S., partially offset by higher demand in Other International. Sales of Veklury are generally affected by coronavirus disease 2019 (“COVID-19”) related rates of infections and hospitalizations as well as the availability, uptake and effectiveness of vaccinations and alternative treatments for COVID-19. As a result, future sales of Veklury are difficult to predict and may vary significantly from one period to the next.

HCV

HCV product sales increased by 22% to \$524 million for the three months ended September 30, 2022, compared to the same period in 2021, primarily due to a favorable resolution of a prior year rebate claim in Europe and other favorable pricing dynamics in the U.S.

HCV product sales decreased by 8% to \$1.4 billion for the nine months ended September 30, 2022, compared to the same period in 2021, primarily due to fewer patient starts and lower average net selling price, partially offset by a favorable resolution of a prior year rebate claim in Europe.

HBV / HDV

HBV and HDV product sales increased by 7% and 4% to \$264 million and \$733 million for the three and nine months ended September 30, 2022, respectively, compared to the same periods in 2021, primarily due to higher demand for Vemlidy and the continued uptake of Hepcludex in Europe.

Cell Therapy

Cell therapy product sales increased by 79% and 65% to \$398 million and \$1.0 billion for the three and nine months ended September 30, 2022, respectively, compared to the same periods in 2021, primarily due to the continued uptake of Yescarta for the treatment of r/r LBCL in the U.S. and Europe. The increase was also driven by higher Tecartus sales volumes resulting from expansion of use in the U.S. and Europe for mantle cell lymphoma and continued adoption in adult patients with r/r ALL in the U.S.

Trodelvy

Trodelvy product sales increased by 78% and 85% to \$180 million and \$485 million for the three and nine months ended September 30, 2022, respectively, compared to the same periods in 2021, primarily due to the continued uptake in the second- and third-line setting for the treatment of metastatic triple-negative breast cancer in the U.S. and Europe as well as second-line metastatic urothelial cancer in the U.S.

Other

Other product sales decreased by 18% and 11% to \$200 million and \$693 million for the three and nine months ended September 30, 2022, respectively, compared to the same periods in 2021, primarily due to lower demand for AmBisome and lower demand for Letairis driven by the loss of exclusivity.

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, 30% and 26% were generated outside the U.S. for the three months ended September 30, 2022 and 2021, respectively. Foreign currency exchange, net of hedges, had an unfavorable impact on our total product sales of \$205 million for the three months ended September 30, 2022, based on a comparison using foreign currency exchange rates from three months ended September 30, 2021.

Of our total product sales, 31% and 30% were generated outside the U.S. for the nine months ended September 30, 2022 and 2021, respectively. Foreign currency exchange, net of hedges, had an unfavorable impact on our total product sales of \$386 million for the nine months ended September 30, 2022, based on a comparison using foreign currency exchange rates from nine months ended September 30, 2021.

Costs and Expenses

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

(in millions, except percentages)	Three Months Ended September 30,			Change	Nine Months Ended September 30,			Change
	2022	2021			2022	2021		
Cost of goods sold	\$ 1,395	\$ 1,223		14 %	\$ 4,261	\$ 3,974		7 %
Product gross margin	80.0 %	83.4 %		-337 bps	78.3 %	80.0 %		-166 bps
Research and development expenses	\$ 1,149	\$ 1,101		4 %	\$ 3,429	\$ 3,243		6 %
Acquired in-process research and development expenses	\$ 448	\$ 65		NM	\$ 786	\$ 270		NM
In-process research and development impairment	\$ —	\$ —		NM	\$ 2,700	\$ —		NM
Selling, general and administrative expenses	\$ 1,213	\$ 1,190		2 %	\$ 3,653	\$ 3,596		2 %

NM - Not Meaningful

Product Gross Margin

Product gross margin for the three months ended September 30, 2022 decreased to 80.0% compared to 83.4% for the same period in 2021, primarily due to a favorable court decision in the third quarter of 2021 that led to the reversal of the previously recorded \$175 million litigation reserve during that period, higher royalty expenses driven by Biktarvy royalties and changes in product mix, partially offset by lower inventory reserve adjustments.

Product gross margin for the nine months ended September 30, 2022 decreased to 78.3% compared to 80.0% for the same period in 2021, primarily due to the reversal of the aforementioned previously recorded litigation reserve following a favorable court decision, higher royalty expenses driven by Biktarvy royalties, changes in product mix and restructuring costs for the closing of a New Jersey manufacturing site, partially offset by lower inventory reserve adjustments.

Research and Development Expenses

Research and development expenses increased by 4% and 6% to \$1.1 billion and \$3.4 billion, for the three and nine months ended September 30, 2022, respectively, compared to the same periods in 2021, primarily due to higher clinical development spend related mostly to Trodelvy and the Arcus Biosciences, Inc. collaboration.

Acquired In-Process Research and Development Expenses

Acquired in-process research and development expenses were \$448 million and \$786 million for the three and nine months ended September 30, 2022, respectively, primarily related to a \$389 million charge associated with our acquisition of MiroBio in September 2022 and a \$300 million upfront payment associated with the collaboration with Dragonfly Therapeutics, Inc., which we entered into in April 2022. Expenses for the three and nine months ended September 30, 2021 were primarily related to smaller licensing, collaboration, investment and other arrangements we entered into during the periods. 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 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 HR+/HER2- metastatic 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, CDK4/6 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. 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. There were no changes in our plans or assumptions related to our estimated cash flows for patients in the earlier lines of therapy. 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. The remaining balance of the IPR&D intangible asset for the HR+/HER2- metastatic breast cancer indication can be ascribed to cash flows from earlier lines of therapy, where we have Phase 3 pivotal studies in development, in addition to the revised cash flows related to the third-line plus patient setting. If future events result in adverse changes in the key assumptions used in determining fair value, including the timing of product launches, information on the competitive landscape of treatments in this indication, changes to the probability of technical or regulatory success, failure to obtain anticipated regulatory approval or discount rate, among others, additional impairments may be recorded and could be material to our financial statements. No other IPR&D impairment charges were recorded during both the three and nine months ended September 30, 2022 and 2021.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the three and nine months ended September 30, 2022 remained relatively unchanged compared to the same periods in 2021. Slightly higher expenses in 2022 related primarily to increased spending on promotional and marketing activities and information technology projects, partially offset by a reduction in donations to the Gilead Foundation.

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 September 30,			Change	Nine Months Ended September 30,			Change
	2022	2021			2022	2021		
Interest expense	\$ (229)	\$ (250)	(9) %		\$ (709)	\$ (763)	(7) %	
Other income (expense), net	\$ (176)	\$ (154)	15 %		\$ (571)	\$ (696)	(18) %	

Interest expense for the three and nine months ended September 30, 2022 decreased by 9% and 7% to \$229 million and \$709 million, respectively, compared to the same periods in 2021, primarily due to lower outstanding debt balances.

The changes in Other income (expense), net for the three and nine months ended September 30, 2022 compared to the same periods in 2021 primarily reflect higher and lower net unrealized losses from equity securities, respectively, 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 September 30,			Nine Months Ended September 30,		
	2022	2021	Change	2022	2021	Change
Income before income taxes	\$ 2,432	\$ 3,438	\$ (1,006)	\$ 3,783	\$ 7,519	\$ (3,736)
Income tax expense	\$ (646)	\$ (852)	\$ (206)	\$ (850)	\$ (1,694)	\$ (844)
Effective tax rate	26.6 %	24.8 %	1.8 %	22.5 %	22.5 %	— %

Our effective tax rate increased for the three months ended September 30, 2022 compared to the same period in 2021, primarily due to \$389 million of non-deductible Acquired in-process research and development expenses recorded in connection with our acquisition of MiroBio.

LIQUIDITY AND CAPITAL RESOURCES

Cash, cash equivalents and marketable debt securities as of September 30, 2022 decreased by \$887 million or 11%, compared to December 31, 2021.

Cash Flows

The following table summarizes our cash flow activities:

(in millions)	Nine Months Ended September 30,	
	2022	2021
Net cash provided by (used in):		
Operating activities	\$ 6,505	\$ 8,179
Investing activities	\$ (2,091)	\$ (2,853)
Financing activities	\$ (4,915)	\$ (6,935)

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 \$6.5 billion for the nine months ended September 30, 2022 compared to \$8.2 billion for the same period in 2021. The decrease was primarily due to the \$1.25 billion payment made in the first quarter of 2022 in connection with the legal settlement related to bictegravir litigation as well as higher income tax payments made in 2022.

Investing Activities

Net cash used in investing activities was \$2.1 billion for the nine months ended September 30, 2022 compared to \$2.9 billion for the same period in 2021. The decrease was primarily due to lower net purchases of marketable debt and equity securities, partially offset by higher capital expenditures.

Financing Activities

Net cash used in financing activities was \$4.9 billion for the nine months ended September 30, 2022 compared to \$6.9 billion for the same period in 2021. During the nine months ended September 30, 2022, we utilized cash for \$1.5 billion of debt repayments, \$2.8 billion of dividend payments and \$604 million of common stock repurchases. During the nine months ended September 30, 2021, we utilized cash for \$3.75 billion of debt repayments, \$2.7 billion of dividend payments and \$497 million of common stock repurchases.

Debt and Credit Facilities

A summary of our borrowing activities, balances and compliance with certain debt covenants under various financing arrangements is included in Note 9. Debt and Credit Facilities of the Notes to Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q. We may choose to repay certain of our long-term debt obligations prior to maturity dates based on our assessment of current and long-term liquidity and capital requirements.

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, 2021. As of January 1, 2022, for U.S. tax purposes, research and development expenses are required to be capitalized and amortized rather than immediately deducted. Absent a change in law, the isolated impact of the required capitalization creates incremental cash tax liabilities. See Notes 6. Acquisitions, Collaborations and Other Arrangements, 9. Debt and Credit Facilities, 10. Commitments and Contingencies and 13. 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 other material changes to our capital resources and material cash requirements during the three and nine months ended September 30, 2022.

CRITICAL ACCOUNTING ESTIMATES

The preparation of our Condensed Consolidated Financial Statements in accordance with U.S. GAAP requires management to make estimates and judgments that affect the reported amounts in the financial statements and related disclosures. On an ongoing basis, we evaluate our significant accounting policies and estimates. We base our estimates on historical experience and on various market-specific and other relevant assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Estimates are assessed each period and updated to reflect current information. Actual results may differ significantly from these estimates. A summary of our critical accounting policies and estimates is presented in Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2021. With the exception of our revised estimates related to our HR+/HER2- IPR&D intangible assets as described in “Result of Operations” above, there were no material changes to our critical accounting policies and estimates during the nine months ended September 30, 2022.

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, 2021. 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 September 30, 2022 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 the 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 September 30, 2022.

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 September 30, 2022, 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.

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 nine months ended September 30, 2022, sales of our HIV products accounted for approximately 63% 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, and any changes to the treatment paradigm for HIV may cause nucleoside-based therapeutics to fall out of favor.

Veklury

We face risks related to our supply and distribution of Veklury, which was approved by the U.S. Food and Drug Administration (“FDA”) in October 2020 as a treatment for patients hospitalized with coronavirus disease 2019 (“COVID-19”), in January 2022 as a treatment for non-hospitalized adult and adolescent patients who are at high risk of progression to severe COVID-19, including hospitalization or death, and in April 2022 as a treatment for pediatric patients who are older than 28 days, weighing at least 3 kg, and are either hospitalized with COVID-19 or have mild-to-moderate COVID-19 and are considered high risk for progression to severe COVID-19, including hospitalization or death. While the utilization of Veklury has largely tracked rates of COVID-19 hospitalizations, we are unable to accurately predict our revenues or supply needs over the short and long term due to the dynamic nature of the pandemic, including the availability, uptake and effectiveness of vaccines and alternative treatments for COVID-19, fluctuating hospital utilization rates, the emergence of new variants and timing of surges in infection. If we do not accurately forecast demand or manufacture Veklury at levels sufficient to meet demand, then we may experience product shortages or build excess inventory that may be written off. We also remain subject to significant public attention and scrutiny over the complex decisions made regarding clinical data, supply, allocation, distribution and pricing of Veklury, all of which affects our corporate reputation.

Cell Therapy

Advancing a novel and personalized therapy such as Tecartus or Yescarta, 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 Tecartus and Yescarta, 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 Tecartus and Yescarta, 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 Tecartus and Yescarta 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 a new automated CAR T-cell therapy manufacturing facility in Frederick, Maryland, which received FDA approval for commercial production in April 2022. 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 new 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 United States, 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 necessarily mirror 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 United States exclusively through the wholesale channel. For the nine months ended September 30, 2022, approximately 90% of our product sales in the United States 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 completely effective 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 technologies which are 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 of third-party payer reimbursement for the cost of such products and related treatments and medical services in the markets where we sell our products. Government health authorities, private health insurers and other organizations generally provide reimbursement. 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 United States, 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. In the United States, the volume of drug pricing-related legislation has dramatically increased in recent years. For example, 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. Also, in August 2022 Congress enacted the Inflation Reduction Act of 2022 (the “Act”), which, among other changes, requires the Department of Health and Human Services to negotiate Medicare prices for certain drugs, imposes an inflation-based rebate on Medicare Part B and D utilization, restructures the Medicare Part D benefit and increase manufacturer contributions in some or all of the Medicare Part D benefit phases. We are continuing to evaluate the impact of the Act on our business, but it is possible that the Act could have the effect of limiting the prices we can charge and increasing the rebates we must provide government programs for our products, thereby reducing our profitability and negatively impacting our financial results. We cannot be sure whether additional legislation or rulemaking related to the Act will be issued or enacted, or what impact, if any, such changes will have on the profitability of our business in the future. In addition, 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 to state agencies, 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 United States, 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 340B covered entities. 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.

We recently implemented a contract pharmacy integrity initiative for our branded hepatitis C virus (“HCV”) products. This integrity initiative will not involve any products from Asegua 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. Although we believe that our integrity initiative complies with the requirements of the 340B statute, 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 United States, 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. For example, 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 United States, Europe 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 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. investigation 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. We also previously announced that FDA placed clinical holds on studies evaluating (i) lenacapavir in combination with islatravir, (ii) injectable lenacapavir and (iii) magrolimab, and issued a complete response letter for our new drug application for lenacapavir. The clinical holds relating to injectable lenacapavir and magrolimab have since been lifted by FDA, and we have resubmitted a new drug application for lenacapavir in response to the complete response letter. See Note 7. Goodwill and Intangible Assets of the Notes to 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 of \$2.7 billion 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 the 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.

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 United States. 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 United States 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 file, for marketing approval in additional countries and for additional indications and products over the next several years. 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 reimbursement, rebates, price reporting, healthcare fraud and abuse, and data privacy and security. In the United States, these laws include anti-kickback and false claims laws, 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 Department of Veterans Affairs and 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 or to alter one or more of our sales or marketing practices. 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 United States 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 before a patent is issued, we may not know if our competitors have filed patent 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.

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 agreements, in some cases, may result in a loss of exclusivity for our patents sooner than we would otherwise expect, and 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 third parties that such parties may claim cover the use of sofosbuvir, axicabtagene ciloleucel or bicitegravir, as well as certain uses of combinations of emtricitabine (“FTC”) and tenofovir disoproxil fumarate (“TDF”) or TAF. 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. For example, a great deal of our liposomal manufacturing expertise, which is a key component of our liposomal technology, is not covered by patents but is instead protected as a trade secret. 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. These matters could require us to pay significant monetary amounts, including royalty payments for past and future sales. For example, on February 1, 2022, we reached an agreement with ViiV Healthcare Company and related parties (collectively, “ViiV”) for a global resolution of all claims related to our sales of Biktarvy, pursuant to which (1) Gilead agreed to make a one-time payment of \$1.25 billion and an ongoing royalty at a rate of 3% on future sales of Biktarvy and the bicitegravir component of bicitegravir-containing products in the United States until October 5, 2027, and (2) ViiV granted Gilead a broad worldwide license and covenant not to sue relating to any past, present or future development or commercialization of bicitegravir.

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, including the ongoing COVID-19 pandemic.

Actual or threatened outbreaks of epidemic, pandemic or contagious diseases, such as COVID-19, may significantly disrupt our global operations and adversely affect our business, financial condition and results of operations. For example, the COVID-19 pandemic has caused significant volatility and uncertainty in U.S. and international markets and has resulted in increased risks and adverse impacts to our operations, including as described below. We are monitoring a number of risks related to the pandemic, including the following:

- **Supply Chain:** The pandemic could result in disruptions to our global supply chain and distribution in the future. For example, quarantines, shelter-in-place and other governmental orders and policies, travel restrictions, airline capacity and route reductions, safety guidelines and health impacts of the pandemic could impact the availability or productivity of products and personnel at manufacturers, distributors, freight carriers and other necessary components of our supply chain. In addition, there may be unfavorable changes in the availability or cost of raw materials, intermediates and other materials necessary for production, which may result in higher costs, disruptions in our supply chain and interruptions in our distribution capabilities.
- **Clinical Trials:** The pandemic has adversely affected and may continue to adversely affect certain of our clinical trials, including our ability to initiate and complete our clinical trials within the anticipated timelines. For ongoing trials, clinical trial sites have imposed restrictions on patient visits to limit risks of possible COVID-19 exposure, and we may experience issues with participant compliance with clinical trial protocols as a result of quarantines, travel restrictions and interruptions to healthcare services. There is also a risk that closures at clinical sites may be necessary as the pandemic and related guidance and restrictions continue to evolve. For the foregoing reasons, we have experienced delays with new subject enrollment for most clinical trials during the course of the pandemic, and may continue to experience overall delays in our clinical trials. There is also the risk of biased data collection if only certain clinical trial sites remain open. As a result of these challenges, our anticipated filing and marketing timelines for certain products may be adversely impacted.
- **Access to Healthcare Providers:** The pandemic has limited patients' ability or willingness to access and seek care from healthcare providers and initiate or continue therapies, which has resulted in lower demand for our products during the course of the pandemic, particularly with respect to HCV treatment and HIV treatment and prevention. For example, we have observed lower levels of patient visits and testing volumes in HCV, resulting in fewer patient starts. In addition, at times during the pandemic, we have seen lower levels of screening and diagnosis for HIV, resulting in fewer treatment initiations, as well as higher levels of discontinuations, resulting in a reduction in prescription refills. With increased levels of unemployment at times during the pandemic, we have also experienced shifts in payer mix towards more government-funded coverage and the uninsured segment. Our field personnel have also had reduced access to healthcare personnel during the pandemic, including fewer in-person interactions, which has adversely impacted and may continue to adversely impact our commercial activities.
- **Employees:** We face risks related to the health, safety, morale and productivity of our employees, including the safe occupancy of our sites during the pandemic. In the fourth quarter of 2021, we transitioned to a return-to-site phase for our U.S. flexible location employees. Our job site enhancements and risk protocols, which include health screenings and COVID-19 testing and vaccine requirements, do not guarantee that we can maintain the continued safe occupancy of our sites and may adversely impact employee recruitment and retention.
- **Financial:** The pandemic has had, and may continue to have, an adverse financial impact in the short term and potentially beyond. For example, we have observed reductions in the overall U.S. HCV treatment, HIV treatment and HIV pre-exposure prophylaxis ("PrEP") volumes at times during the pandemic. We may continue to experience fluctuating revenues as infection rates rise and fall and as pandemic restrictions are periodically tightened and eased. We have also experienced, and may continue to experience, volatility in our short-term revenues due to fluctuations in inventory channel purchases during the pandemic. We could also have additional unexpected expenses related to the pandemic, which could negatively affect our results of operations. These factors together with the overall uncertainty and disruption caused by the pandemic could result in increased volatility and decreased predictability in our results of operations and volatility in our stock price.

The pandemic has also amplified many of the other risks described throughout the “Risk Factors” section of this Quarterly Report on Form 10-Q. The extent to which the pandemic impacts our business and results will depend on future developments, which are uncertain and cannot be predicted with confidence, including any potential future waves of the pandemic, new variants of the virus that impact the severity and duration of the pandemic, the development, distribution, effectiveness and public acceptance of vaccines, and any other ongoing and future actions taken to contain the pandemic.

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 nine months ended September 30, 2022, approximately 31% of our product sales were outside the United States. 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 have been and may continue to be adversely impacted if the U.S. dollar continues to appreciate significantly against certain currencies and our hedging program does not sufficiently offset the effects of such appreciation. For example, see 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 three and nine months ended September 30, 2022.
- **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, could also 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 United States 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, the 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. For example, we have collaboration arrangements with Janssen Sciences Ireland UC for Odefsey, Complera/Eviplera and Syntuza. 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.

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, malicious intrusion and ransomware attack. Likewise, data privacy or security 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. Cybersecurity incidents are increasing in their frequency, sophistication and intensity. Cybersecurity incidents include, for example, the deployment of harmful malware, ransomware, denial-of-service, social engineering and other means to affect service reliability 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 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, including, in some cases, healthcare data or other 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, and may not realize the expected benefits. 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 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 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. 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 transactions, 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 United States 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 United States, 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**

The table below summarizes our stock repurchase activity for the three months ended September 30, 2022:

	Total Number of Shares Purchased (in thousands)	Average Price Paid per Share (in dollars)	Total Number of Shares Purchased as Part of Publicly Announced Program ⁽¹⁾ (in thousands)	Maximum Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs ⁽¹⁾ (in millions)
July 1 - July 31, 2022	887	\$ 61.62	842	\$ 5,793
August 1 - August 31, 2022	1,627	\$ 63.08	1,112	\$ 5,723
September 1 - September 30, 2022	1,058	\$ 64.65	899	\$ 5,665
Total	3,572 ⁽²⁾	\$ 63.18	2,853 ⁽²⁾	

Certain amounts may not sum due to rounding.

⁽¹⁾ In the first quarter of 2016, our Board of Directors authorized a \$12.0 billion share repurchase program ("2016 Program"), with no fixed expiration. Shares purchased during the period were made under the 2016 Program. In January 2020, our Board of Directors authorized a new \$5.0 billion stock repurchase program, with no fixed expiration, which will commence upon the completion of the 2016 Program. Share repurchases under both programs may be made in the open market or in privately negotiated transactions.

⁽²⁾ 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

Not applicable.

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>
(1)	3.2	<u>Amended and Restated Bylaws of Registrant</u>
	4.1	Reference is made to Exhibit 3.1 and Exhibit 3.2
(2)	4.2	<u>Indenture related to Senior Notes, dated as of March 30, 2011, between Registrant and Wells Fargo, National Association, as Trustee</u>
(2)	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>
(3)	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>
(4)	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>
(5)	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>
(6)	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>
(7)	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>
(8)	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>
(9)	4.10	<u>Description of Registrant's Securities</u>
(10)	10.1*	<u>Gilead Sciences, Inc. 2004 Equity Incentive Plan, amended and restated May 10, 2017</u>
(11)	10.2*	<u>Amendment No. 1 to Gilead Sciences, Inc. 2004 Equity Incentive Plan, amended and restated May 10, 2017</u>
(12)	10.3*	<u>Gilead Sciences, Inc. 2022 Equity Incentive Plan</u>
(13)	10.4*	<u>Form of employee stock option agreement under 2004 Equity Incentive Plan (for grants made in 2011 through 2018)</u>
(14)	10.5*	<u>Form of employee stock option agreement under 2004 Equity Incentive Plan (for grants made in 2019)</u>
(15)	10.6*	<u>Form of global employee stock option agreement under 2004 Equity Incentive Plan (4 year vest) (for grants made in 2019)</u>
(16)	10.7*	<u>Form of global employee stock option agreement under 2004 Equity Incentive Plan (4 year vest) (for grants made in 2020)</u>
(17)	10.8*	<u>Form of global employee stock option agreement under 2004 Equity Incentive Plan (4 year vest) (for grants made in 2021)</u>
(18)	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>
(19)	10.10*	<u>Form of global employee stock option agreement under 2022 Equity Incentive Plan (4 year vest) (for certain grants commencing in 2022)</u>
(20)	10.11*	<u>Form of non-employee director stock option agreement under 2004 Equity Incentive Plan (for grants made in 2009 through 2012)</u>
(21)	10.12*	<u>Form of non-employee director stock option agreement (U.S.) under 2004 Equity Incentive Plan (for grants made in 2013)</u>
(21)	10.13*	<u>Form of non-employee director stock option agreement (non-U.S.) under 2004 Equity Incentive Plan (for grants made in 2013)</u>
(22)	10.14*	<u>Form of non-employee director stock option agreement under 2004 Equity Incentive Plan (for grants made in 2014 through 2018)</u>
(14)	10.15*	<u>Form of non-employee director stock option agreement under 2004 Equity Incentive Plan (for grants made in 2019)</u>
(23)	10.16*	<u>Form of non-employee director stock option agreement under 2004 Equity Incentive Plan (for grants made in 2020 and 2021)</u>
(19)	10.17*	<u>Form of non-employee director stock option agreement under 2022 Equity Incentive Plan (for grants commencing in 2022)</u>
(14)	10.18*	<u>Form of performance share award agreement - TSR Goals (U.S.) under 2004 Equity Incentive Plan (for grants made in 2019)</u>
(16)	10.19*	<u>Form of performance share award agreement - TSR Goals (U.S.) under 2004 Equity Incentive Plan (for grants made in 2020)</u>
(17)	10.20*	<u>Form of performance share award agreement - TSR Goals (U.S.) under 2004 Equity Incentive Plan (for grants made in 2021)</u>
(18)	10.21*	<u>Form of performance share award agreement - TSR Goals (U.S.) under 2004 Equity Incentive Plan (for grants commencing in 2022)</u>
(14)	10.22*	<u>Form of performance share award agreement - Revenue Goals (U.S.) under 2004 Equity Incentive Plan (for grants made in 2019)</u>
(16)	10.23*	<u>Form of performance share award agreement - Revenue Goals (U.S.) under 2004 Equity Incentive Plan (for grants made in 2020)</u>
(21)	10.24*	<u>Form of performance share award agreement - Revenue Goals (U.S.) under 2004 Equity Incentive Plan (for grants made in 2021)</u>

(18)	10.25*	<u>Form of performance share award agreement - Revenue Goals (U.S.) under 2004 Equity Incentive Plan (for grants commencing in 2022)</u>
(13)	10.26*	<u>Form of employee restricted stock unit issuance agreement under 2004 Equity Incentive Plan (for grants made in 2011 through 2018)</u>
(14)	10.27*	<u>Form of employee restricted stock unit issuance agreement under 2004 Equity Incentive Plan (for grants made in 2019)</u>
(15)	10.28*	<u>Form of global employee restricted stock unit issuance agreement under 2004 Equity Incentive Plan (4 year vest) (for grants made in 2019)</u>
(16)	10.29*	<u>Form of global employee restricted stock unit issuance agreement under 2004 Equity Incentive Plan (4 year vest) (for grants made in 2020)</u>
(17)	10.30*	<u>Form of global employee restricted stock unit issuance agreement under 2004 Equity Incentive Plan (4 year vest) (for grants made in 2021)</u>
(18)	10.31*	<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>
(19)	10.32*	<u>Form of global employee restricted stock unit agreement under 2022 Equity Incentive Plan (4 year vest) (for certain grants commencing in 2022)</u>
(23)	10.33*	<u>Form of non-employee director restricted stock unit issuance agreement under 2004 Equity Incentive Plan (for grants made in 2020 and 2021)</u>
(19)	10.34*	<u>Form of non-employee director restricted stock unit agreement under 2022 Equity Incentive Plan (for grants commencing in 2022)</u>
(23)	10.35*	<u>Gilead Sciences, Inc. 2018 Equity Incentive Plan, amended and restated April 7, 2020</u>
(24)	10.36*	<u>Gilead Sciences, Inc. Employee Stock Purchase Plan, amended and restated January 22, 2015</u>
(14)	10.37*	<u>Gilead Sciences, Inc. 2005 Deferred Compensation Plan, amended and restated April 19, 2016</u>
(23)	10.38*	<u>Gilead Sciences, Inc. Severance Plan, amended and restated May 5, 2020</u>
(16)	10.39*	<u>Gilead Sciences, Inc. Corporate Annual Incentive Plan, amended and restated January 1, 2020</u>
(26)	10.40*	<u>Offer Letter between Registrant and Daniel O' Day, dated November 30, 2018</u>
(14)	10.41*	<u>Stock option agreement for Daniel O' Day under 2004 Equity Incentive Plan</u>
(14)	10.42*	<u>Performance share award agreement for Daniel O' Day (for TSR Goals in 2019) under 2004 Equity Incentive Plan</u>
(14)	10.43*	<u>Performance share award agreement for Daniel O' Day (for Revenue Goals in 2019) under 2004 Equity Incentive Plan</u>
(14)	10.44*	<u>Form of restricted stock unit issuance agreement for Daniel O' Day (in 2019) under 2004 Equity Incentive Plan</u>
(14)	10.45*	<u>Offer Letter between Registrant and Johanna Mercier, dated May 21, 2019</u>
(23)	10.46*	<u>Letter Agreement between Registrant and Johanna Mercier, dated May 4, 2020</u>
(16)	10.47*	<u>Global stock option agreement for Johanna Mercier (in 2019) under 2004 Equity Incentive Plan</u>
(16)	10.48*	<u>Restricted stock unit issuance agreement for Johanna Mercier (for Performance Objectives in 2019-2020) under 2004 Equity Incentive Plan</u>
(16)	10.49*	<u>Global restricted stock unit issuance agreement for Johanna Mercier (in 2019) under 2004 Equity Incentive Plan</u>
(16)	10.50*	<u>Offer Letter between Registrant and Merdad Parsey, dated September 29, 2019</u>
(16)	10.51*	<u>Global stock option agreement for Merdad Parsey (in 2019) under 2004 Equity Incentive Plan</u>
(16)	10.52*	<u>Global restricted stock unit issuance agreement for Merdad Parsey (in 2019) under 2004 Equity Incentive Plan</u>
(27)	10.53*	<u>Form of Indemnity Agreement entered into between Registrant and its directors and executive officers</u>
(27)	10.54*	<u>Form of Employee Proprietary Information and Invention Agreement entered into between Registrant and certain of its officers and key employees</u>
(28)	10.55*	<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>
+(29)	10.56	<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>
+(30)	10.57	<u>Amendment Agreement between Registrant and IOCB/REGA, dated December 27, 2000, amending the 1991 License Agreement and the December 1992 License Agreement</u>
+(31)	10.58	<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>
+(32)	10.59	<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>
+(33)	10.60	<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>
+(34)	10.61	<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>

+ (34)	10.62	<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>
++ (35)	10.63	<u>Amended and Restated EVG License Agreement by and between Japan Tobacco Inc. and Registrant, dated November 29, 2018</u>
++ (35)	10.64	<u>Master Agreement by and between Registrant, Gilead Sciences K.K. and Japan Tobacco Inc., dated November 29, 2018</u>
+ (36)	10.65	<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 23, 2014</u>
+ (37)	10.66	<u>License Agreement by and among Kite Pharma, Inc., Cabaret Biotech Ltd. and Dr. Zelig Eshhar, dated December 12, 2013</u>
++ (15)	10.67	<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)
<p>(1) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on May 9, 2019, and incorporated herein by reference.</p> <p>(2) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on April 1, 2011, and incorporated herein by reference.</p> <p>(3) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on December 13, 2011, and incorporated herein by reference.</p> <p>(4) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on March 7, 2014, and incorporated herein by reference.</p> <p>(5) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on November 17, 2014, and incorporated herein by reference.</p> <p>(6) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on September 14, 2015, and incorporated herein by reference.</p> <p>(7) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on September 20, 2016, and incorporated herein by reference.</p> <p>(8) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on September 30, 2020, and incorporated herein by reference.</p> <p>(9) 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.</p> <p>(10) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on May 12, 2017, and incorporated herein by reference.</p> <p>(11) 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.</p> <p>(12) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on May 5, 2022, and incorporated herein by reference.</p> <p>(13) 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.</p> <p>(14) 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.</p> <p>(15) 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.</p> <p>(16) 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.</p> <p>(17) 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.</p> <p>(18) 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.</p> <p>(19) 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.</p> <p>(20) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2009, and incorporated herein by reference.</p> <p>(21) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, and incorporated herein by reference.</p> <p>(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.</p> <p>(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.</p> <p>(24) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on May 8, 2015, and incorporated herein by reference.</p> <p>(25) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2018, and incorporated herein by reference.</p> <p>(26) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on December 10, 2018, and incorporated herein by reference.</p> <p>(27) Filed as an exhibit to Registrant's Registration Statement on Form S-1 (No. 33-55680), as amended, and incorporated herein by reference.</p> <p>(28) 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.</p> <p>(29) 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.</p> <p>(30) 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.</p> <p>(31) 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.</p> <p>(32) 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.</p> <p>(33) 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.</p> <p>(34) 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.</p> <p>(35) 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.</p> <p>(36) 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.</p> <p>(37) 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.</p> <p>* Management contract or compensatory plan or arrangement.</p> <p>** Filed herewith.</p> <p>*** Furnished herewith.</p> <p>+ 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.</p> <p>++ 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.</p>		

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: November 2, 2022

/s/ DANIEL P. O'DAY

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

Date: November 2, 2022

/s/ ANDREW D. DICKINSON

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