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, 2021

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	**94-3047598**
(State or Other Jurisdiction of Incorporation or Organization)	(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 x 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 x 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 x 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 x

Number of shares outstanding of the issuer's common stock, par value $0.001 per share, as of October 29, 2021: 1,254,383,522

GILEAD SCIENCES, INC.

INDEX

We own or have rights to various trademarks, copyrights 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® (BULEVIRTIDE), HEPSERA®, JYSELECA®, LETAIRIS®, ODEFSEY®, RANEXA®, SOVALDI®, STRIBILD®, TECARTUS®, TRODELVY®, TRUVADA®, TRUVADA FOR PREP®, TYBOST®, VEKLURY®, VEMLIDY®, VIREAD®, VOSEVI®, YESCARTA® and ZYDELIG®. This report also includes other trademarks, service marks and trade names of other companies.

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, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 4,362	$ 5,997
Short-term marketable securities	1,376	1,411
Accounts receivable, net	4,566	4,892
Inventories	1,676	1,683
Prepaid and other current assets	2,011	2,013
Total current assets	13,991	15,996
Property, plant and equipment, net	5,037	4,967
Long-term marketable securities	1,099	502
Intangible assets, net	33,900	33,126
Goodwill	8,332	8,108
Other long-term assets	4,739	5,708
Total assets	$ 67,098	$ 68,407
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 585	$ 844
Accrued government and other rebates	3,368	3,460
Accrued and other current liabilities	3,781	4,336
Current portion of long-term debt and other obligations, net	2,511	2,757
Total current liabilities	10,245	11,397
Long-term debt, net	25,175	28,645
Long-term income taxes payable	4,642	5,016
Deferred tax liability	4,603	3,914
Other long-term obligations	962	1,214
Commitments and contingencies (Note 11)		
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; 1,255 and 1,254 shares issued and outstanding, respectively	1	1
Additional paid-in capital	4,492	3,880
Accumulated other comprehensive income (loss)	74	(60)
Retained earnings	16,903	14,381
Total Gilead stockholders' equity	21,470	18,202
Noncontrolling interest	1	19
Total stockholders' equity	21,471	18,221
Total liabilities and stockholders' equity	$ 67,098	$ 68,407

See accompanying notes.

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

(in millions, except per share amounts)	Three Months Ended September 30, 2021	Three Months Ended September 30, 2020	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020
Revenues:				
Product sales	$ 7,356	$ 6,493	$ 19,848	$ 17,027
Royalty, contract and other revenues	65	84	213	241
Total revenues	7,421	6,577	20,061	17,268
Costs and expenses:				
Cost of goods sold	1,223	1,141	3,974	3,174
Research and development expenses	1,147	1,158	3,336	3,461
Acquired in-process research and development expenses	19	1,171	177	5,792
Selling, general and administrative expenses	1,190	1,106	3,596	3,421
Total costs and expenses	3,579	4,576	11,083	15,848
Income from operations	3,842	2,001	8,978	1,420
Interest expense	(250)	(236)	(763)	(717)
Other income (expense), net	(154)	(940)	(696)	(848)
Income (loss) before income taxes	3,438	825	7,519	(145)
Income tax expense	(852)	(472)	(1,694)	(1,310)
Net income (loss)	2,586	353	5,825	(1,455)
Net loss attributable to noncontrolling interest	6	7	18	27
Net income (loss) attributable to Gilead	$ 2,592	$ 360	$ 5,843	$ (1,428)
Net income (loss) per share attributable to Gilead common stockholders - basic	$ 2.06	$ 0.29	$ 4.65	$ (1.14)
Shares used in per share calculation - basic	1,256	1,255	1,256	1,257
Net income (loss) per share attributable to Gilead common stockholders - diluted	$ 2.05	$ 0.29	$ 4.63	$ (1.14)
Shares used in per share calculation - diluted	1,262	1,261	1,262	1,257

See accompanying notes.

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

(in millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net income (loss)	$ 2,586	$ 353	$ 5,825	$ (1,455)
Other comprehensive income (loss):				
Net foreign currency translation gain (loss), net of tax	(20)	23	(15)	(12)
Available-for-sale debt securities:				
Net unrealized gain (loss), net of tax	—	(9)	(3)	42
Reclassifications to net income (loss), net of tax	—	(4)	—	(17)
Net change	—	(13)	(3)	25
Cash flow hedges:				
Net unrealized gain (loss), net of tax	37	(46)	92	(25)
Reclassifications to net income (loss), net of tax	18	(11)	60	(50)
Net change	55	(57)	152	(75)
Other comprehensive income (loss)	35	(47)	134	(62)
Comprehensive income (loss)	2,621	306	5,959	(1,517)
Comprehensive loss attributable to noncontrolling interest	6	7	18	27
Comprehensive income (loss) attributable to Gilead	$ 2,627	$ 313	$ 5,977	$ (1,490)

See accompanying notes.

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

	Three Months Ended September 30, 2021						
	Gilead Stockholders' Equity						
	Common Stock						
(in millions, except per share amounts)	Shares	Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income	Retained Earnings	Noncontrolling Interest	Total Stockholders' Equity
Balance at 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 at September 30, 2021	1,255	$ 1	$ 4,492	$ 74	$ 16,903	$ 1	$ 21,471

	Nine Months Ended September 30, 2021						
	Gilead Stockholders' Equity						
	Common Stock						
(in millions, except per share amounts)	Shares	Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Retained Earnings	Noncontrolling Interest	Total Stockholders' Equity
Balance at 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 at September 30, 2021	1,255	$ 1	$ 4,492	$ 74	$ 16,903	$ 1	$ 21,471

See accompanying notes.

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

	Three Months Ended September 30, 2020						
	Gilead Stockholders' Equity						
	Common Stock						
(in millions, except per share amounts)	Shares	Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Retained Earnings	Noncontrolling Interest	Total Stockholders' Equity
Balance at June 30, 2020	1,254	$ 1	$ 3,511	$ 70	$ 14,445	$ 115	$ 18,142
Change in noncontrolling interest	—	—	—	—	—	(82)	(82)
Net income (loss)	—	—	—	—	360	(7)	353
Other comprehensive income (loss), net of tax	—	—	1	(47)	(1)	—	(47)
Issuances under employee stock purchase plan	1	—	34	—	—	—	34
Issuances under equity incentive plans	2	—	2	—	—	—	2
Stock-based compensation	—	—	173	—	—	—	173
Repurchases of common stock	(4)	—	(9)	—	(229)	—	(238)
Dividends declared ($0.68 per share)	—	—	—	—	(866)	—	(866)
Balance at September 30, 2020	1,253	$ 1	$ 3,712	$ 23	$ 13,709	$ 26	$ 17,471

	Nine Months Ended September 30, 2020						
	Gilead Stockholders' Equity						
	Common Stock						
(in millions, except per share amounts)	Shares	Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Retained Earnings	Noncontrolling Interest	Total Stockholders' Equity
Balance at December 31, 2019	1,266	$ 1	$ 3,051	$ 85	$ 19,388	$ 125	$ 22,650
Cumulative effect from the adoption of new accounting standard	—	—	—	—	(7)	—	(7)
Change in noncontrolling interest	—	—	—	—	—	(72)	(72)
Net loss	—	—	—	—	(1,428)	(27)	(1,455)
Other comprehensive income (loss), net of tax	—	—	1	(62)	(1)	—	(62)
Issuances under employee stock purchase plan	2	—	100	—	—	—	100
Issuances under equity incentive plans	10	—	148	—	—	—	148
Stock-based compensation	—	—	482	—	—	—	482
Repurchases of common stock	(25)	—	(70)	—	(1,644)	—	(1,714)
Dividends declared ($2.04 per share)	—	—	—	—	(2,599)	—	(2,599)
Balance at September 30, 2020	1,253	$ 1	$ 3,712	$ 23	$ 13,709	$ 26	$ 17,471

See accompanying notes.

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

(in millions)	Nine Months Ended September 30, 2021	2020
Operating Activities:		
Net income (loss)	$ 5,825	$ (1,455)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation expense	239	209
Amortization expense	1,276	844
Stock-based compensation expense	476	482
Acquired in-process research and development expenses	177	5,792
Deferred income taxes	243	(12)
Net loss from equity securities	667	1,046
Other	601	210
Changes in operating assets and liabilities:		
Accounts receivable, net	272	(334)
Inventories	(24)	(48)
Prepaid expenses and other	(17)	22
Accounts payable	(242)	(134)
Income taxes payable	(463)	(428)
Accrued and other liabilities	(851)	58
Net cash provided by operating activities	8,179	6,252
Investing Activities:		
Purchases of marketable debt securities	(2,891)	(19,809)
Proceeds from sales of marketable debt securities	506	12,367
Proceeds from maturities of marketable debt securities	1,808	8,528
Acquisitions, including in-process research and development, net of cash acquired	(1,401)	(5,804)
Purchases of equity securities	(332)	(388)
Capital expenditures	(423)	(469)
Other	(120)	(63)
Net cash used in investing activities	(2,853)	(5,638)
Financing Activities:		
Proceeds from debt financing, net of issuance costs	—	7,189
Proceeds from issuances of common stock	157	248
Repurchases of common stock	(497)	(1,583)
Repayments of debt and other obligations	(3,750)	(2,500)
Payments of dividends	(2,711)	(2,591)
Other	(134)	(124)
Net cash provided by (used in) financing activities	(6,935)	639
Effect of exchange rate changes on cash and cash equivalents	(26)	2
Net change in cash and cash equivalents	(1,635)	1,255
Cash and cash equivalents at beginning of period	5,997	11,631
Cash and cash equivalents at end of period	$ 4,362	$ 12,886

See accompanying notes.

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying unaudited Condensed Consolidated Financial Statements have been prepared in accordance with U.S. generally accepted accounting principles for interim financial information. The financial statements include all adjustments consisting of normal recurring adjustments that the management of Gilead Sciences, Inc. ("Gilead," "we," "our" or "us") believes are necessary for a fair presentation of the periods presented. These interim financial results are not necessarily indicative of results expected for the full fiscal year or for any subsequent interim period.

The accompanying Condensed Consolidated Financial Statements include the accounts of Gilead, our wholly-owned subsidiaries and a variable interest entity ("VIE") for which we are the primary beneficiary. All intercompany transactions have been eliminated. For consolidated entities where we own or are exposed to less than 100% of the economics, we record net income (loss) attributable to noncontrolling interests in our Condensed Consolidated Statements of Operations equal to the percentage of the economic or ownership interest retained in such entities by the respective noncontrolling parties.

We assess whether we are the primary beneficiary of a VIE at the inception of the arrangement and at each reporting date. This assessment is based on our power to direct the activities of the VIE that most significantly impact the VIE's economic performance and our obligation to absorb losses or the right to receive benefits from the VIE that could potentially be significant to the VIE. We did not have any material VIEs as of September 30, 2021.

The accompanying Condensed Consolidated Financial Statements and related Notes to Condensed Consolidated Financial Statements should be read in conjunction with the audited Consolidated Financial Statements and the related notes thereto for the year ended December 31, 2020, included in our Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission.

Segment Information

We have one operating segment, which focuses on the discovery, development and commercialization of innovative medicines in areas of unmet medical need. Our Chief Executive Officer, as the chief operating decision-maker ("CODM"), manages and allocates resources to the operations of the company on an entity-wide basis. Managing and allocating resources on an entity-wide basis enables our CODM to assess the overall level of resources available and how to best deploy these resources across functions and research and development ("R&D") projects based on unmet medical need and, as necessary, reallocate resources among our internal R&D portfolio and external opportunities to best support the long-term growth of our business. See Note 2. Revenues for a summary of disaggregated revenues by product and geographic region.

Significant Accounting Policies, Estimates and Judgments

The preparation of these Condensed Consolidated Financial Statements in accordance with U.S. generally accepted accounting principles requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses 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, such as the economic considerations related to the impact that the coronavirus disease 2019 ("COVID-19") could have on our significant accounting estimates. Actual results may differ significantly from these estimates.

Concentrations of Risk

We are subject to credit risk from our portfolio of cash equivalents and marketable securities. Under our investment policy, we limit amounts invested in such securities by credit rating, maturity, industry group, investment type and issuer, except for securities issued by the U.S. government. We are not exposed to any significant concentrations of credit risk from these financial instruments. The goals of our investment policy, in order of priority, are as follows: safety and preservation of principal and diversification of risk; liquidity of investments sufficient to meet cash flow requirements; and a competitive after-tax rate of return.

We are also subject to credit risk from our accounts receivable related to our product sales. Trade accounts receivable are recorded net of allowances for wholesaler chargebacks related to government and other programs, cash discounts for prompt payment and credit losses. Estimates of our allowance for credit losses consider a number of factors, including existing contractual payment terms, individual customer circumstances, historical payment patterns of our customers, a review of the local economic environment and its potential impact on expected future customer payment patterns and government funding and reimbursement practices. The majority of our trade accounts receivable arises from product sales in the United States and Europe. There were no material write-offs charged against the allowance for the three and nine months ended September 30, 2021 and 2020.

2. REVENUES

Disaggregation of Revenues

Revenues were as follows:

(in millions)	Three Months Ended September 30, 2021				Three Months Ended September 30, 2020			
	U.S.	Europe	Other International	Total	U.S.	Europe	Other International	Total
Product Sales:								
HIV								
Atripla	$ 21	$ 2	$ 4	$ 27	$ 99	$ 5	$ 9	$ 113
Biktarvy	1,875	254	147	2,276	1,584	194	113	1,891
Complera/Eviplera	28	31	5	64	26	35	9	70
Descovy	355	42	36	433	424	49	35	508
Genvoya	576	100	68	744	669	116	61	846
Odefsey	275	112	12	399	309	116	12	437
Stribild	28	11	3	42	27	13	2	42
Truvada	55	5	7	67	492	6	11	509
Revenue share - Symtuza[1]	86	41	3	130	82	34	2	118
Other HIV[2]	3	4	—	7	10	1	2	13
Total HIV	3,302	602	285	4,189	3,722	569	256	4,547
Hepatitis C virus ("HCV")								
Ledipasvir/Sofosbuvir[3]	14	5	26	45	36	11	37	84
Sofosbuvir/Velpatasvir[4]	173	77	82	332	170	74	86	330
Other HCV[5]	37	12	3	52	35	13	2	50
Total HCV	224	94	111	429	241	98	125	464
Hepatitis B virus ("HBV") / Hepatitis Delta virus ("HDV")								
Vemlidy	103	9	96	208	99	8	70	177
Viread	1	7	18	26	3	8	21	32
Other HBV/HDV[6]	—	13	—	13	—	2	—	2
Total HBV/HDV	104	29	114	247	102	18	91	211
Veklury	1,527	109	287	1,923	785	60	28	873
Cell Therapy								
Tecartus	35	12	—	47	5	4	—	9
Yescarta	100	66	9	175	85	51	2	138
Total Cell Therapy	135	78	9	222	90	55	2	147
Trodelvy	100	1	—	101	—	—	—	—
Other								
AmBisome	7	67	69	143	18	58	35	111
Letairis	46	—	—	46	78	—	—	78
Zydelig	6	7	—	13	8	9	—	17
Other[7]	28	10	5	43	32	10	3	45
Total Other	87	84	74	245	136	77	38	251
Total product sales	5,479	997	880	7,356	5,076	877	540	6,493
Royalty, contract and other revenues	30	34	1	65	24	60	—	84
Total revenues	$ 5,509	$ 1,031	$ 881	$ 7,421	$ 5,100	$ 937	$ 540	$ 6,577

(in millions)	Nine Months Ended September 30, 2021 U.S.	Europe	Other International	Total	Nine Months Ended September 30, 2020 U.S.	Europe	Other International	Total
Product Sales:								
HIV								
Atripla	$ 96	$ 10	$ 12	$ 118	$ 275	$ 17	$ 19	$ 311
Biktarvy	4,926	707	461	6,094	4,346	528	314	5,188
Complera/Eviplera	73	104	12	189	77	124	17	218
Descovy	994	128	105	1,227	1,124	156	103	1,383
Genvoya	1,633	306	184	2,123	1,927	376	183	2,486
Odefsey	773	336	39	1,148	851	341	36	1,228
Stribild	94	33	12	139	100	42	12	154
Truvada	268	18	24	310	1,245	20	37	1,302
Revenue share - Symtuza[1]	261	125	8	394	244	112	6	362
Other HIV[2]	14	9	12	35	24	4	21	49
Total HIV	9,132	1,776	869	11,777	10,213	1,720	748	12,681
HCV								
Ledipasvir/Sofosbuvir[3]	63	24	76	163	113	26	124	263
Sofosbuvir/Velpatasvir[4]	649	234	272	1,155	646	253	330	1,229
Other HCV[5]	97	64	9	170	100	37	12	149
Total HCV	809	322	357	1,488	859	316	466	1,641
HBV / HDV								
Vemlidy	266	25	298	589	248	22	194	464
Viread	8	22	55	85	10	27	100	137
Other HBV/HDV[6]	1	29	—	30	9	6	—	15
Total HBV/HDV	275	76	353	704	267	55	294	616
Veklury	2,763	761	684	4,208	785	60	28	873
Cell Therapy								
Tecartus	94	25	—	119	5	5	—	10
Yescarta	300	188	25	513	283	144	7	434
Total Cell Therapy	394	213	25	632	288	149	7	444
Trodelvy	261	1	—	262	—	—	—	—
Other								
AmBisome	32	202	186	420	46	166	113	325
Letairis	157	—	—	157	241	—	—	241
Ranexa	5	—	—	5	9	—	—	9
Zydelig	22	27	1	50	24	30	1	55
Other[7]	82	41	22	145	103	32	7	142
Total Other	298	270	209	777	423	228	121	772
Total product sales	13,932	3,419	2,497	19,848	12,835	2,528	1,664	17,027
Royalty, contract and other revenues	70	140	3	213	55	170	16	241
Total revenues	$ 14,002	$ 3,559	$ 2,500	$ 20,061	$ 12,890	$ 2,698	$ 1,680	$ 17,268

(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.
(2) Includes 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 and Jyseleca.

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:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(as a percentage of total revenues)	2021	2020	2021	2020
AmerisourceBergen Corporation	25 %	30 %	24 %	25 %
Cardinal Health, Inc.	22 %	19 %	21 %	22 %
McKesson Corporation	21 %	22 %	18 %	22 %

Revenues Recognized from Performance Obligations Satisfied in Prior Periods

Revenues recognized from performance obligations satisfied in prior years related to royalties for licenses of our intellectual property were $190 million and $625 million for the three and nine months ended September 30, 2021, respectively, and $206 million and $618 million for the three and nine months ended September 30, 2020, respectively.

Variable consideration is included in the net sales price only to the extent a significant reversal in the amount of cumulative revenue recognized is not probable of occurring when the uncertainty associated with the variable consideration is subsequently resolved. Estimates are assessed each period and updated to reflect current information. Changes in estimates for variable consideration related to sales made in prior years resulted in a $188 million and $661 million increase in revenues for the three and nine months ended September 30, 2021, respectively, and $13 million and $94 million increase in revenues for the three and nine months ended September 30, 2020, respectively.

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 $167 million and $198 million as of September 30, 2021 and December 31, 2020, respectively. Contract liabilities, which generally result from receipt of advance payment before our performance under the contract, were $85 million and $97 million as of September 30, 2021 and December 31, 2020, respectively. During the three and nine months ended September 30, 2021 and 2020, revenue recognized that was included in the contract liability balance as of the beginning of the respective years was not material. Revenue expected to be recognized in the future from contract liabilities as the related performance obligations are satisfied is not expected to be material in any one year.

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

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, 2021				December 31, 2020			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Assets:								
Available-for-sale debt securities:								
U.S. treasury securities	$ 360	$ —	$ —	$ 360	$ 309	$ —	$ —	$ 309
U.S. government agencies securities	—	5	—	5	—	—	—	—
Non-U.S. government securities	—	44	—	44	—	43	—	43
Certificates of deposit	—	361	—	361	—	216	—	216
Corporate debt securities	—	1,272	—	1,272	—	1,142	—	1,142
Residential mortgage and asset-backed securities	—	447	—	447	—	316	—	316
Equity securities:								
Money market funds	2,768	—	—	2,768	4,361	—	—	4,361
Equity investment in Galapagos	881	—	—	881	1,648	—	—	1,648
Other publicly traded equity securities[1]	876	—	—	876	743	—	—	743
Deferred compensation plan	249	—	—	249	218	—	—	218
Foreign currency derivative contracts	—	55	—	55	—	12	—	12
Total	$ 5,134	$ 2,184	$ —	$ 7,318	$ 7,279	$ 1,729	$ —	$ 9,008
Liabilities:								
Liability for MYR GmbH (“MYR”) contingent consideration	$ —	$ —	$ 328	$ 328	$ —	$ —	$ —	$ —
Deferred compensation plan	249	—	—	249	218	—	—	218
Foreign currency derivative contracts	—	8	—	8	—	121	—	121
Total	$ 249	$ 8	$ 328	$ 585	$ 218	$ 121	$ —	$ 339

[1] Includes our equity investment in Arcus Biosciences, Inc. (“Arcus”) of $482 million as of September 30, 2021 recorded in Prepaid and other current assets and $212 million as of December 31, 2020 recorded in Other long-term assets on our Condensed Consolidated Balance Sheets. See Note 9. Collaborations and Other Arrangements for further information.

Equity Securities

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

(in millions)	September 30, 2021	December 31, 2020
Cash and cash equivalents	$ 2,768	$ 4,361
Prepaid and other current assets[1]	871	853
Other long-term assets[1]	1,135	1,756
Total	$ 4,774	$ 6,970

[1] See the table under the Equity Investment in Galapagos NV (“Galapagos”) for more information.

Changes in the fair value of equity securities resulted in net unrealized loss of $142 million and $667 million for the three and nine months ended September 30, 2021, respectively, and $964 million and $1.0 billion for the three and nine months ended September 30, 2020, respectively, which were included in Other income (expense), net on our Condensed Consolidated Statements of Operations.

Our available-for-sale debt securities are classified as cash equivalents, short-term marketable securities and long-term marketable securities in our Condensed Consolidated Balance Sheets. See Note 4. Available-For-Sale Debt Securities for additional information.

Equity Investment in Galapagos

The following table summarizes the classification of our equity investment in Galapagos in our Condensed Consolidated Balance Sheets:

(in millions)	September 30, 2021	December 31, 2020
Prepaid and other current assets	$ —	$ 351
Other long-term assets	881	1,297
Total	$ 881	$ 1,648

We elected and applied the fair value option to account for our equity investment in Galapagos whereby the investment is marked to market through earnings each reporting period based on the market price of Galapagos shares. We believe the fair value option best reflects the underlying economics of the investment. The portion of the investment subject to long-term contractual lock-up provisions is classified within Other long-term assets and the remainder is classified as Prepaid and other current assets on our Condensed Consolidated Balance Sheets. In April 2021, we amended the Galapagos subscription agreement to extend the initial lock-up provision for certain Galapagos shares from August 2021 to August 2024. As of September 30, 2021, all of our equity investment in Galapagos was classified as Other long-term assets on our Condensed Consolidated Balance Sheets.

Other Equity Securities

Equity investments not measured at fair value and excluded from the above tables were limited partnerships and other equity method investments of $96 million and $58 million at September 30, 2021 and December 31, 2020, respectively, and other equity investments without readily determinable fair values of $211 million and $204 million at September 30, 2021 and December 31, 2020, respectively. These amounts were included in Other long-term assets on our Condensed Consolidated Balance Sheets.

Related Party Transaction

During the second quarter of 2021, Gilead donated certain equity securities at fair value to the Gilead Foundation, a California nonprofit organization (the "Foundation"). The Foundation is a related party as certain officers of the Company also serve as directors of the Foundation. The donation expense of $212 million was recorded within Selling, general and administrative expenses on our Condensed Consolidated Statements of Operations during the nine months ended September 30, 2021.

Level 2 Inputs

We estimate the fair values of Level 2 financial instruments by taking into consideration valuations obtained from third-party pricing services. The pricing services utilize industry standard valuation models, including both income-based and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate the fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities, issuer credit spreads, benchmark securities, prepayment/default projections based on historical data and other observable inputs.

For our marketable securities, we review trading activity and pricing as of the measurement date. When sufficient quoted pricing for identical securities is not available, we use market pricing and other observable market inputs for similar securities obtained from various third-party data providers. These inputs either represent quoted prices for similar assets in active markets or have been derived from observable market data.

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, London Interbank Offered Rates ("LIBOR") and swap rates. These inputs, where applicable, are observable at commonly quoted intervals.

The total estimated fair values of our aggregate short-term and long-term debt, determined using Level 2 inputs based on their quoted market values, were approximately $29.6 billion and $34.6 billion as of September 30, 2021 and December 31, 2020, respectively, and the carrying values were $26.6 billion and $30.3 billion as of September 30, 2021 and December 31, 2020, respectively.

Level 3 Inputs

We measured assets acquired and liabilities assumed at fair value as of the acquisition on a nonrecurring basis, in connection with our first quarter 2021 acquisition of MYR. The liability for contingent consideration of $341 million as of the acquisition date is remeasured on a recurring basis. The estimated fair value of this contingent liability was $328 million as of September 30, 2021. The change in estimated fair value from the acquisition date was primarily due to the effect of foreign exchange remeasurement. The contingent consideration was estimated using probability-weighted scenarios for U.S. Food and Drug Administration ("FDA") approval of Hepcludex. See Note 6. Acquisitions for additional information.

We measured assets acquired and liabilities assumed at fair value as of the acquisition on a nonrecurring basis, in connection with our fourth quarter 2020 acquisition of Immunomedics, Inc. ("Immunomedics"). The liability related to future royalties assumed is recorded at amortized cost, which approximated fair value as of September 30, 2021 and December 31, 2020. See Note 6. Acquisitions and Note 10. Debt and Credit Facilities for additional information.

4. AVAILABLE-FOR-SALE DEBT SECURITIES

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

	September 30, 2021				December 31, 2020			
(in millions)	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	$ 360	$ —	$ —	$ 360	$ 308	$ 1	$ —	$ 309
U.S. government agencies securities	5	—	—	5	—	—	—	—
Non-U.S. government securities	44	—	—	44	43	—	—	43
Certificates of deposit	361	—	—	361	216	—	—	216
Corporate debt securities	1,272	1	(1)	1,272	1,140	2	—	1,142
Residential mortgage and asset-backed securities	447	—	—	447	316	—	—	316
Total	$ 2,489	$ 1	$ (1)	$ 2,489	$ 2,023	$ 3	$ —	$ 2,026

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

(in millions)	September 30, 2021	December 31, 2020
Cash and cash equivalents	$ 14	$ 113
Short-term marketable securities	1,376	1,411
Long-term marketable securities	1,099	502
Total	$ 2,489	$ 2,026

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

	September 30, 2021	
(in millions)	Amortized Cost	Fair Value
Within one year	$ 1,390	$ 1,390
After one year through five years	1,075	1,075
After five years	24	24
Total	$ 2,489	$ 2,489

We held a total of 214 and 208 positions which were in unrealized loss positions as of September 30, 2021 and 2020, respectively. The unrealized losses were largely due to changes in interest rates. Aggregated gross unrealized losses on available-for-sale debt securities were not material for the three and nine months ended September 30, 2021 and 2020. No impairment was recognized for the three and nine months ended September 30, 2021 and 2020.

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 may hedge a portion of our foreign currency exposure related to outstanding monetary assets and liabilities as well as forecasted product sales using foreign currency exchange forward or option 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.

We hedge our exposure to foreign currency exchange rate fluctuations for certain monetary assets and liabilities that are denominated in a non-functional currency. The derivative instruments we use to hedge this exposure 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 Operations.

We hedge our exposure to foreign currency exchange rate fluctuations for forecasted product sales that are denominated in a non-functional currency. The derivative instruments we use to hedge this exposure are designated as cash flow hedges and have maturities of 18 months or less. Upon executing a hedging contract and quarterly thereafter, we assess hedge effectiveness using regression analysis. The unrealized gains or losses in Accumulated other comprehensive income (“AOCI”) are reclassified into product sales 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, 2021 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, 2021 and 2020 were included within Net cash provided by operating activities on our Condensed Consolidated Statements of Cash Flows.

We had notional amounts on foreign currency exchange contracts outstanding of $3.0 billion and $2.4 billion as of September 30, 2021 and December 31, 2020, respectively.

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 on our Condensed Consolidated Balance Sheets:

	September 30, 2021			
	Derivative Assets		Derivative Liabilities	
(in millions)	Classification	Fair Value	Classification	Fair Value
Derivatives designated as hedges:				
Foreign currency exchange contracts	Prepaid and other current assets	$ 50	Accrued and other current liabilities	$ (8)
Foreign currency exchange contracts	Other long-term assets	5	Other long-term obligations	—
Total derivatives designated as hedges		55		(8)
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		$ 55		$ (8)

	December 31, 2020			
	Derivative Assets		Derivative Liabilities	
(in millions)	Classification	Fair Value	Classification	Fair Value
Derivatives designated as hedges:				
Foreign currency exchange contracts	Prepaid and other current assets	$ —	Accrued and other current liabilities	$ (113)
Foreign currency exchange contracts	Other long-term assets	—	Other long-term obligations	(7)
Total derivatives designated as hedges		—		(120)
Derivatives not designated as hedges:				
Foreign currency exchange contracts	Prepaid and other current assets	12	Accrued and other current liabilities	(1)
Total derivatives not designated as hedges		12		(1)
Total derivatives		$ 12		$ (121)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in millions)	2021	2020	2021	2020
Derivatives designated as hedges:				
Gains (losses) recognized in AOCI	$ 42	$ (52)	$ 104	$ (28)
Gains (losses) reclassified from AOCI into product sales	$ (21)	$ 12	$ (69)	$ 57
Derivatives not designated as hedges:				
Gains (losses) recognized in Other income (expense), net	$ 5	$ (13)	$ 24	$ (10)

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 Operations. There were no discontinuances of cash flow hedges for the three and nine months ended September 30, 2021 and 2020.

As of September 30, 2021 and December 31, 2020, we only held foreign currency exchange contracts. The following table summarizes the potential effect of offsetting our foreign currency exchange contracts on our Condensed Consolidated Balance Sheets:

				Gross Amounts Not Offset on our Condensed Consolidated Balance Sheets		
(in millions)	Gross Amounts of Recognized Assets/Liabilities	Gross Amounts Offset on our Condensed Consolidated Balance Sheets	Amounts of Assets/Liabilities Presented on our Condensed Consolidated Balance Sheets	Derivative Financial Instruments	Cash Collateral Received/ Pledged	Net Amount (Legal Offset)
As of September 30, 2021						
Derivative assets	$ 55	$ —	$ 55	$ (7)	$ —	$ 48
Derivative liabilities	$ (8)	$ —	$ (8)	$ 7	$ —	$ (1)
As of December 31, 2020						
Derivative assets	$ 12	$ —	$ 12	$ (12)	$ —	$ —
Derivative liabilities	$ (121)	$ —	$ (121)	$ 12	$ —	$ (109)

6. ACQUISITIONS

We account for business combinations using the acquisition method of accounting, which generally requires that assets acquired, including in-process research and development ("IPR&D") projects, and liabilities assumed be recorded at their fair values as of the acquisition date on our Condensed Consolidated Balance Sheets. Any excess of consideration over the fair value of net assets acquired is recorded as goodwill. Transaction costs associated with business combinations are expensed as they are incurred. The first quarter 2021 acquisition of MYR and the fourth quarter 2020 acquisition of Immunomedics were accounted for as business combinations.

When the net assets acquired do not meet the definition of a business combination under the acquisition method of accounting, the transaction is accounted for as an acquisition of assets. For an asset acquisition, no goodwill is recorded and contingent consideration, such as payments upon achievement of various development, regulatory and commercial milestones, generally is not recognized as of the acquisition date. In an asset acquisition, upfront payments allocated to IPR&D projects at the acquisition date and subsequent milestone payments are expensed unless there is an alternative future use. The second quarter 2020 acquisition of Forty Seven, Inc. ("Forty Seven") was accounted for as an asset acquisition.

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. Upon closing, MYR became a wholly-owned subsidiary of Gilead. The financial results of MYR were included in our Condensed Consolidated Financial Statements from the date of the acquisition. Acquisition-related expenses were not material for the three and nine months ended September 30, 2021.

The aggregate consideration for this acquisition of €1.3 billion (or $1.6 billion) primarily consists 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 and was initially recorded in Other long-term obligations on our Condensed Consolidated Balance Sheets. In the second quarter of 2021, the balance was reclassified to Accrued and other current liabilities on our Condensed Consolidated Balance Sheets. The estimated fair value of the contingent liability was $328 million as of September 30, 2021. The change in estimated fair value from the acquisition date was primarily due to the effect of foreign exchange remeasurement.

The fair value estimates for the assets acquired and liabilities assumed were based upon valuations using information known and knowable as of the date of this filing. Changes to these assumptions and estimates could cause an impact to the valuation of assets acquired, including intangible assets, goodwill and the related tax impacts of the acquisition, as well as legal and other contingencies. The amounts recognized will be finalized as the information necessary to complete the analysis is obtained, but no later than one year after the acquisition date.

The following table summarizes estimated fair values of assets acquired and liabilities assumed as of the acquisition date:

(in millions)	Amount
Intangible assets:	
Finite-lived intangible asset	$ 845
Acquired IPR&D	1,190
Deferred income taxes, net	(513)
Other assets (and liabilities), net	(187)
Total identifiable net assets	1,335
Goodwill	226
Total consideration	$ 1,561

Intangible Assets

The finite-lived intangible asset of $845 million represents the estimated fair value of Hepcludex for HDV in Europe as of the acquisition date. The fair value was determined by applying the income approach using unobservable inputs to estimate probability-weighted net cash flows attributable to Hepcludex for HDV in Europe and a discount rate of 12%. The discount rate used represents the estimated rate that market participants would use to value this intangible asset. This intangible asset is being amortized over an estimated useful life of 10 years.

Acquired intangible assets related to IPR&D consist of Hepcludex for HDV in all other regions without regulatory approval, including the United States. The estimated aggregate fair value of $1.2 billion as of the acquisition date was determined by applying the income approach using unobservable inputs to estimate probability-weighted net cash flows attributable to this asset and a discount rate of 12%. The discount rate used represents the estimated rate that market participants would use to value this intangible asset.

Some of the more significant assumptions inherent in the development of intangible asset fair values include: estimates of projected future cash flows including revenues and operating profits; probability of success; the discount rate selected; the life of the potential commercialized products and the risks related to the viability of and potential alternative treatments in any future target markets, among other factors.

Intangible assets related to IPR&D projects are considered to be indefinite-lived assets until the completion or abandonment of the associated R&D efforts.

The inputs used for valuing these identifiable intangibles are unobservable and considered Level 3 under the fair value measurement and disclosure guidance. See Note 3. Fair Value Measurements for additional information.

Deferred Income Taxes

The net deferred tax liability was based upon the difference between the estimated book basis and tax basis of net assets acquired and an estimate for the final pre-acquisition net operating losses of MYR.

Goodwill

The excess of the consideration transferred over the fair values of assets acquired and liabilities assumed of $226 million was recorded as goodwill, which primarily reflects the future economic benefits arising from other assets acquired that could not be individually identified and separately recognized. Goodwill recognized for MYR is not expected to be deductible for income tax purposes.

There were no material measurement period adjustments recorded to the fair values of assets acquired and liabilities assumed during the three and nine months ended September 30, 2021.

Immunomedics

In the fourth quarter of 2020, we completed the acquisition of Immunomedics, a company focused on the development of antibody-drug conjugate technology, for cash consideration of $20.6 billion. Upon closing, Immunomedics became a wholly-owned subsidiary of Gilead. The acquisition was financed with the majority of the proceeds from the September 2020 senior unsecured notes offering, an additional $1.0 billion borrowing under a new senior unsecured term loan facility and cash on hand. During the nine months ended September 30, 2021, we repaid the borrowing under the senior unsecured term loan facility. See Note 10. Debt and Credit Facilities for further information.

The following table summarizes estimated fair values of assets acquired and liabilities assumed as of the acquisition date:

(in millions)	Amount
Cash and cash equivalents	$ 726
Inventories	946
Intangible assets:	
Finite-lived intangible asset	4,600
Acquired IPR&D	15,760
Outlicense contract	175
Deferred tax liabilities	(4,565)
Liability related to future royalties	(1,100)
Other assets (and liabilities), net	64
Total identifiable net assets	16,606
Goodwill	3,991
Total consideration transferred	$ 20,597

There were no material measurement period adjustments recorded to the fair values of assets acquired and liabilities assumed during the three and nine months ended September 30, 2021.

Forty Seven

In the second quarter of 2020, we completed the acquisition of Forty Seven, a clinical-stage immuno-oncology company focused on developing therapies targeting cancer immune evasion pathways and specific cell targeting approaches, for total consideration of $4.7 billion, net of acquired cash. Upon closing, Forty Seven became a wholly-owned subsidiary of Gilead. During the nine months ended September 30, 2020, we recorded a $4.5 billion charge representing an acquired IPR&D asset with no alternative future use in Acquired in-process research and development expenses, and stock-based compensation expense of $144 million primarily in Research and development expenses on our Condensed Consolidated Statements of Operations.

7. GOODWILL AND INTANGIBLE ASSETS

Goodwill

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

(in millions)	Amount
Balance at December 31, 2020	$ 8,108
Goodwill resulting from the acquisition of MYR	226
Measurement period adjustments	(2)
Balance at September 30, 2021	$ 8,332

Intangible Assets

The following table summarizes our Intangible assets, net:

	September 30, 2021				December 31, 2020			
(in millions)	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	$ (5,477)	$ —	$ 5,243	$ 10,720	$ (4,952)	$ —	$ 5,768
Intangible asset - axicabtagene ciloleucel[1]	7,110	(1,400)	—	5,710	6,200	(1,105)	—	5,095
Intangible asset - Trodelvy[2]	5,630	(390)	—	5,240	4,600	(63)	—	4,537
Intangible asset - Hepcludex	845	(50)	—	795	—	—	—	—
Other	1,410	(619)	1	792	1,377	(540)	(1)	836
Total finite-lived assets	25,715	(7,936)	1	17,780	22,897	(6,660)	(1)	16,236
Indefinite-lived assets - IPR&D[1][2][3][4]	16,120	—	—	16,120	16,890	—	—	16,890
Total intangible assets	$ 41,835	$ (7,936)	$ 1	$ 33,900	$ 39,787	$ (6,660)	$ (1)	$ 33,126

(1) Gross carrying amount as of September 30, 2021 includes $910 million reclassified from indefinite-lived assets - IPR&D following the March 2021 FDA approval of Yescarta for the treatment of adult patients with relapsed or refractory follicular lymphoma.

(2) Gross carrying amount as of September 30, 2021 includes Trodelvy for metastatic triple-negative breast cancer which was granted approval by FDA in April 2021 and Trodelvy for use in adult patients with locally advanced or metastatic urothelial cancer (“UC”) which was granted accelerated approval by FDA in April 2021. The amount related to UC of $1.0 billion was reclassified to finite-lived assets from indefinite-lived assets - IPR&D.

(3) Gross carrying amount as of September 30, 2021 includes $1.2 billion recognized from the first quarter 2021 acquisition of MYR. See Note 6. Acquisitions for additional information.

(4) In October 2021, FDA granted approval of Tecartus for the treatment of adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia. Accordingly, the related amount of $200 million will be reclassified to finite-lived assets in the fourth quarter of 2021.

Aggregate amortization expense related to finite-lived intangible assets was $441 million and $1.3 billion for the three and nine months ended September 30, 2021 and $281 million and $844 million for the three and nine months ended September 30, 2020, respectively, and was primarily included in Cost of goods sold on our Condensed Consolidated Statements of Operations.

The following table summarizes the estimated future amortization expense associated with our finite-lived intangible assets as of September 30, 2021:

(in millions)	Amount
2021 (remaining three months)	$ 441
2022	1,764
2023	1,764
2024	1,764
2025	1,759
Thereafter	10,288
Total	$ 17,780

8. OTHER FINANCIAL INFORMATION

Accounts receivable, net

The following table summarizes our Accounts receivable, net:

(in millions)	September 30, 2021	December 31, 2020
Accounts receivable	$ 5,284	$ 5,560
Less: chargebacks	591	552
Less: cash discounts and other	70	72
Less: allowances for credit losses	57	44
Accounts receivable, net	$ 4,566	$ 4,892

Inventories

The following table summarizes our Inventories:

(in millions)	September 30, 2021	December 31, 2020
Raw materials	$ 1,067	$ 1,080
Work in process	727	976
Finished goods	1,003	958
Total	$ 2,797	$ 3,014
Reported as:		
Inventories	$ 1,676	$ 1,683
Other long-term assets[1]	1,121	1,331
Total	$ 2,797	$ 3,014

[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, 2021	December 31, 2020
Compensation and employee benefits	$ 691	$ 864
Income taxes payable	447	598
Allowance for sales returns	530	587
Other accrued liabilities	2,113	2,287
Total	$ 3,781	$ 4,336

9. COLLABORATIONS AND OTHER ARRANGEMENTS

We continue to pursue licensing and strategic collaborations and other similar arrangements with third parties for the development and commercialization of certain products and product candidates. These 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 and cost-sharing arrangements. We also continue to pursue equity investments in third parties focused on the development and commercialization of products and product candidates.

Merck Sharp & Dohme Corp. ("Merck")

On March 13, 2021, we entered into a license and collaboration agreement with Merck, a subsidiary of Merck & Co., Inc. to jointly develop and commercialize long-acting investigational treatments in HIV that combine Gilead's investigational capsid inhibitor, lenacapavir, and Merck's investigational nucleoside reverse transcriptase translocation inhibitor, islatravir. The collaboration will initially focus on long-acting oral and injectable formulations.

Under the terms of the agreement, Gilead and Merck will share global development and commercialization costs at 60% and 40%, respectively, across the oral and injectable formulation programs. For long-acting oral products, Gilead will lead commercialization in the United States, and Merck will lead commercialization in the European Union ("EU") and rest of the world. For long-acting injectable products, Merck will lead commercialization in the United States and Gilead will lead commercialization in the EU and rest of the world. Gilead and Merck will jointly promote the combination products in the United States and certain other major markets. We will share global product revenues with Merck equally until product revenues surpass certain pre-determined per formulation revenue tiers. Upon passing $2.0 billion in net product sales for the oral combination in a given calendar year, our share of revenue will increase to 65% for any revenues above the threshold for such calendar year. Upon passing $3.5 billion in net product sales for the injectable combination in a given calendar year, our share of revenue will increase to 65% for any revenues above the threshold for such calendar year. Reimbursements of research and development costs to or from Merck are recorded within Research and development expenses on our Condensed Consolidated Statements of Operations. Expenses recognized under the agreement were not material for the three and nine months ended September 30, 2021. No revenues have been recognized under the agreement for the three and nine months ended September 30, 2021.

We will also have the option to license certain of Merck's investigational oral integrase inhibitors to develop in combination with lenacapavir. Reciprocally, Merck will have the option to license certain of Gilead's investigational oral integrase inhibitors to develop in combination with islatravir. Each company may exercise its option for such investigational oral integrase inhibitor of the other company within the first five years after execution of the agreement, following completion of the first Phase 1 clinical trial of that integrase inhibitor. Upon exercise of an option, the companies will split development costs and revenues, unless the non-exercising company decides to opt-out, in which case the non-exercising company will be paid a royalty.

Arcus

On May 27, 2020, we entered into a transaction with Arcus, which included entry into an option, license and collaboration agreement (the "Collaboration Agreement") and a common stock purchase agreement and an investor rights agreement (together, and as subsequently amended the "Stock Purchase Agreements"). Under the Stock Purchase Agreements, we have the right to purchase additional shares of Arcus from Arcus over the five-year period beginning on the closing of the Stock Purchase Agreements, up to a maximum of 35% of the outstanding voting stock. We are subject to a three-year standstill, which period began on the date the parties entered into the Stock Purchase Agreements, restricting our ability to acquire voting stock of Arcus exceeding more than 35% of the then issued and outstanding voting stock of Arcus, subject to certain exceptions. Additionally, we agreed not to dispose of any equity securities of Arcus prior to the second anniversary of the closing of the Stock Purchase Agreements without the prior consent of Arcus, subject to certain exceptions.

Pursuant to the Collaboration Agreement and Stock Purchase Agreements which closed on July 13, 2020, and a separate secondary equity offering which closed on May 29, 2020, we acquired approximately 8.2 million shares of Arcus common stock for approximately $261 million. In the first quarter of 2021, we amended and restated the common stock purchase agreement and acquired approximately 5.7 million additional shares of Arcus common stock for $220 million. As a result, we currently own a total of 13.8 million shares of Arcus, which represented approximately 19.5% of the issued and outstanding voting stock of Arcus immediately following the closing of the first quarter 2021 transaction. The amendment and restatement of the common stock purchase agreement in the first quarter of 2021 did not modify any of the terms above. We elected and applied the fair value option to account for our equity investment in Arcus whereby the investment is marked to market each reporting period based on the market price of Arcus shares. We believe the fair value option best reflects the underlying economics of the investment. Changes in fair value of the investment are recognized in Other income (expense), net on our Condensed Consolidated Statements of Operations. We initially recorded our equity investments in Arcus in Other long-term assets on our Condensed Consolidated Balance Sheets as the investments are subject to contractual lock-up provisions, subject to certain conditions. In the third quarter of 2021, we reclassified our equity investments in Arcus to Prepaid and other current assets on our Condensed Consolidated Balance Sheets as the contractual lock-up provisions will expire in July 2022.

Other Arrangements

During the three and nine months ended September 30, 2021 and 2020, we entered into several collaborations, equity investments and licensing arrangements as well as other similar arrangements that we do not consider to be individually material. We recorded upfront collaboration expenses related to these arrangements within Acquired in-process research and development expenses on our Condensed Consolidated Statements of Operations. Upfront collaboration expenses and cash payments made related to our equity investments were not material for the three and nine months ended September 30, 2021 and 2020.

Under the financial terms of these arrangements, we may be required to make payments upon achievement of developmental, regulatory and commercial milestones, which could be significant. Future milestone payments, if any, will be reflected in our Condensed Consolidated Statements of Operations when the corresponding events become probable. In addition, we may be required to pay significant royalties on future sales if products related to these arrangements are commercialized. The payment of these amounts, however, is contingent upon the occurrence of various future events, which have a high degree of uncertainty of occurrence.

10. 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, 2021	December 31, 2020
Senior Unsecured	March 2011	April 2021	4.50%	$ —	$ 1,000
Senior Unsecured	September 2020	September 2021	3-month LIBOR + 0.15%	—	499
Senior Unsecured	December 2011	December 2021	4.40%	—	1,249
Senior Unsecured	September 2016	March 2022	1.95%	500	499
Senior Unsecured	September 2015	September 2022	3.25%	999	998
Senior Unsecured	September 2016	September 2023	2.50%	748	748
Senior Unsecured	September 2020	September 2023	3-month LIBOR + 0.52%	499	498
Senior Unsecured	September 2020	September 2023	0.75%	1,994	1,992
Term Loan	October 2020	October 2023	variable	—	998
Senior Unsecured	March 2014	April 2024	3.70%	1,747	1,746
Senior Unsecured	November 2014	February 2025	3.50%	1,747	1,746
Senior Unsecured	September 2015	March 2026	3.65%	2,738	2,737
Senior Unsecured	September 2016	March 2027	2.95%	1,246	1,246
Senior Unsecured	September 2020	October 2027	1.20%	746	745
Senior Unsecured	September 2020	October 2030	1.65%	992	992
Senior Unsecured	September 2015	September 2035	4.60%	992	991
Senior Unsecured	September 2016	September 2036	4.00%	742	741
Senior Unsecured	September 2020	October 2040	2.60%	987	986
Senior Unsecured	December 2011	December 2041	5.65%	996	996
Senior Unsecured	March 2014	April 2044	4.80%	1,736	1,735
Senior Unsecured	November 2014	February 2045	4.50%	1,733	1,732
Senior Unsecured	September 2015	March 2046	4.75%	2,220	2,219
Senior Unsecured	September 2016	March 2047	4.15%	1,727	1,726
Senior Unsecured	September 2020	October 2050	2.80%	1,476	1,476
Total senior unsecured notes and term loan facility				26,565	30,295
Liability related to future royalties				1,121	1,107
Total debt, net				27,686	31,402
Less: current portion of long-term debt and other obligations, net				2,511	2,757
Total long-term debt, net				$ 25,175	$ 28,645

Debt

During the nine months ended September 30, 2021, we repaid $3.75 billion of debt. We repaid $1.0 billion of senior unsecured notes due April 2021 in the first quarter of 2021 and $1.25 billion of senior unsecured notes due December 2021 in the third quarter of 2021. Additionally, we repaid $1.0 billion principal amount outstanding under our three-year $1.0 billion senior unsecured term loan facility due October 2023 and $500 million of our senior unsecured floating rate notes due September 2021 upon maturity. In October 2021, we exercised our option to call $500 million of our floating rate senior unsecured notes and $500 million of our 0.75% senior unsecured notes, both having a final maturity of September 2023. The notes will be repaid in November 2021.

No new debt was issued during the three and nine months ended September 30, 2021. We are required to comply with certain covenants under our note indentures governing our senior unsecured notes. As of September 30, 2021, we were in compliance with all covenants.

Credit Facility

As of September 30, 2021 and December 31, 2020, 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.

11. COMMITMENTS AND CONTINGENCIES

Legal Proceedings

We are a party to various legal actions. The most significant of these 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, it is not possible to determine the outcome of these matters or the outcome (including in excess of any accrual) is not expected to be material, and we cannot reasonably estimate the maximum potential exposure or the range of possible loss. In the third quarter of 2021, we reversed a $175 million previously recorded litigation accrual following a favorable court decision.

We did not have any material accruals for the matters described below on our Condensed Consolidated Balance Sheets as of September 30, 2021 and December 31, 2020.

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 the 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 concludes the inter partes review that it has 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. We believe that the amended EP '190 patent claims are invalid. Subsequently, we initiated proceedings to invalidate the UK 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 UK counterpart and seeking damages and other relief. 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 other relief. The hearing date for the German NuCana case has been scheduled for May 2022.

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 on 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 up-front 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. We believe that the likelihood of a material adverse outcome in this matter is remote.

Litigation Related to Bictegravir

In 2018, ViiV Healthcare Company ("ViiV") filed a lawsuit against us in the U.S. District Court of Delaware, alleging that the commercialization of bictegravir, sold commercially in combination with tenofovir alafenamide and emtricitabine as Biktarvy, infringes ViiV's U.S. Patent No. 8,129,385 (the "'385 patent") covering ViiV's dolutegravir. Bictegravir is structurally different from dolutegravir, and we believe that bictegravir does not infringe the claims of the '385 patent. The court has set a trial date of January 2022 for this lawsuit. ViiV is seeking billions of dollars for alleged damages comprised of ViiV's lost profits and a royalty on sales of bictegravir from launch through the trial. ViiV calculates these damages based on the cumulative U.S. revenues from Biktarvy since launch, which have totaled $16.4 billion through September 30, 2021. In addition, should a court find that we are liable for infringement, we expect ViiV will seek a royalty on sales after the trial. Although we cannot predict with certainty the ultimate outcome of this litigation, an adverse judgment could result in substantial monetary damages, including ViiV's lost profits and royalties through trial, and a going-forward royalty stream on future sales.

In 2018, ViiV also filed a lawsuit against us in the Federal Court of Canada, alleging that our activities relating to our bictegravir compound have infringed ViiV's Canadian Patent No. 2,606,282 (the "'282 patent"), which was issued to Shionogi & Co. Ltd. and ViiV. The '282 patent is the compound patent covering ViiV's dolutegravir. We believe that bictegravir does not infringe the claims of the '282 patent. In January 2020, the court held a summary trial to assess ViiV's infringement allegations. In April 2020, the court determined that bictegravir does not infringe the claims of the '282 patent and dismissed the case. ViiV appealed this decision, and in June 2021, the Canadian Federal Court of Appeal upheld the Federal Court of Canada's decision. ViiV has sought leave to appeal to the Canadian Supreme Court.

In November and December 2019, ViiV filed lawsuits in France, Germany, Ireland and the UK asserting the relevant national designations of European Patent No. 3 045 206 ("EP '206"); in Australia asserting Australian Patent No. 2006239177; in Japan asserting Japanese Patent No. 4295353; and in Korea asserting Korean Patent Nos. 1848819 ("KR '819") and 1363875. These patents all relate to molecules that ViiV claims would act as integrase inhibitors. We believe that bictegravir does not infringe the claims of any of ViiV's patents. In 2019, we filed an opposition in the EPO requesting revocation of EP '206. The EPO hearing took place in January 2021, and the patent claims, which do not cover bictegravir, were maintained in amended form. Both parties have appealed this decision. Additionally, in 2020, we filed a petition in the Korean Intellectual Property Office requesting invalidation of KR '819. Following a trial, a tribunal of the Korean Intellectual Property Trial and Appeal Board found KR '819 to be invalid. In March 2021, ViiV appealed this decision. In April 2021, the court in Germany held a hearing on the issue of infringement, and in September 2021, determined that Gilead does not infringe ViiV's EP '206 patent both in its original form and as amended by the EPO. ViiV has appealed this decision.

In all jurisdictions, to the extent that the claims of ViiV's patents are interpreted to cover bictegravir, we believe that those claims are invalid. We cannot predict the ultimate outcome of intellectual property claims related to bictegravir.

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 or TDF 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 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 date for the lawsuit in the Court of Federal Claims has been set for June 2022, and a trial date for the lawsuit in the District Court of Delaware 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 earlier than 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., Apotex Inc., Shilpa Medicare Ltd., Sunshine Lake Pharma Co. Ltd., Laurus Labs, Natco Pharma Ltd., Macleods Pharma Ltd., Hetero Labs Ltd. and Cipla Ltd. (collectively, "generic manufacturers") indicating that they have submitted ANDAs to FDA requesting permission to market and manufacture generic versions of certain of our tenofovir alafenamide ("TAF")-containing products. Between them, these generic manufacturers seek to market generic versions of Odefsey, Descovy and Vemlidy. Some generic manufacturers have challenged the validity of four patents listed on the Orange Book and associated with TAF, while others have challenged the validity of two of our Orange Book-listed patents associated with TAF. We filed lawsuits against the generic manufacturers, and we intend to enforce and defend our intellectual property.

In October 2021, we received a letter from Lupin Ltd. indicating that it has submitted an ANDA to the FDA requesting permission to market and manufacture a generic version of Symtuza. We are evaluating the letter and intend to enforce and defend our intellectual property.

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 originally scheduled for July 2021 has been canceled and a new date has not yet been set by the EPO.

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. Two of the original opposing parties have appealed, requesting full revocation.

In 2016, several parties filed oppositions in the EPO requesting revocation of our granted European patent covering TAF that expires in 2026. In 2017, the EPO upheld the validity of the claims of our TAF patent. Three parties have appealed this decision. The appeal hearing was held in March 2021, and the validity of all claims were upheld.

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.

In 2016, three parties filed oppositions in the EPO requesting revocation of our granted European patent covering cobicistat that expires in 2027. In 2017, the EPO upheld the validity of the claims of our cobicistat patent. Two parties have appealed this decision.

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, TAF hemifumarate and cobicistat in the European Union 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 Japan Tobacco, Inc. ("Japan Tobacco"), 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. Japan Tobacco was dismissed from the lawsuit after a favorable court ruling on the defendants' motion to dismiss. Plaintiffs allege that we (and the other remaining 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 end-payor purchasers, including health insurers and individual patients. Plaintiffs seek damages, permanent injunctive relief and other relief. In September 2021, we, along with BMS and generic manufacturer Teva Pharmaceuticals USA ("Teva"), were named as defendants in similar lawsuits filed by CVS, Rite Aid, Walgreens, Safeway, Kroger, Albertsons and HEB (the "Retailers") in the U.S. District Court for the Northern District of California. The Retailers are opting out of the proposed direct purchaser class and, based on assignments by their wholesalers, seek to bring claims substantially the same as the putative class.

In September 2020, we, along with generic manufacturers Cipla Ltd. and Cipla USA Inc. (together, "Cipla"), 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 Cipla, 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 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 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, Missouri and New Jersey, involve more than 24,000 plaintiffs. Plaintiffs in these cases seek damages and other relief on various grounds for alleged personal injury and economic loss. 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 relator served us with a Second Amended Complaint in January 2021. The lawsuit alleges that Gilead's HCV patient access programs, clinical educator programs, speaker programs, and other sales and marketing programs violated the federal False Claims Act and various state false claims acts. In July 2021, the relator filed a Third Amended Complaint, removing allegations against us regarding our patient access programs, clinical educator programs and relationships with specialty pharmacies. The relator seeks all available relief under these statutes.

Two former employees filed a qui tam lawsuit against Gilead in April 2020 in California state court. These same former employees had previously filed a qui tam lawsuit in federal court in California, and the U.S. Department of Justice declined intervention and moved to dismiss relators' federal False Claims Act claims. Relators subsequently voluntarily dismissed their federal lawsuit and refiled their lawsuit in California state court. Following the California Attorney General's Office's decision not to intervene, relators served Gilead with their complaint in August 2020. The complaint alleges violations of the California False Claims Act ("CFCA") and employment law claims. Relators seek all available relief under the CFCA.

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. The case is stayed 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. 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 business, financial position or results of operations.

12. 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 new $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.

During the three and nine months ended September 30, 2021, we repurchased and retired 2.1 million and 7.5 million shares of our common stock for $145 million and $497 million, respectively, through open market transactions under the 2016 Program. During the three and nine months ended September 30, 2020, we repurchased and retired 3.0 million and 22.4 million shares of our common stock for $201 million and $1.6 billion, respectively, through open market transactions under the 2016 Program.

As of September 30, 2021, the remaining authorized repurchase amount under both programs was $6.3 billion.

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 at December 31, 2020	$ 51	$ 2	$ (113)	$ (60)
Net unrealized gain (loss)	(15)	(3)	92	74
Reclassifications to net income (loss)	—	—	60	60
Net current period other comprehensive income (loss)	(15)	(3)	152	134
Balance at September 30, 2021	$ 36	$ (1)	$ 39	$ 74

(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 at December 31, 2019	$ 53	$ 1	$ 31	$ 85
Net unrealized gain (loss)	(12)	42	(25)	5
Reclassifications to net income (loss)	—	(17)	(50)	(67)
Net current period other comprehensive income (loss)	(12)	25	(75)	(62)
Balance at September 30, 2020	$ 41	$ 26	$ (44)	$ 23

The amounts reclassified to net income (loss) for gains and losses on cash flow hedges are recorded as part of Product sales on our Condensed Consolidated Statements of Operations. See Note 5. Derivative Financial Instruments for additional information. The amounts reclassified to net income (loss) 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 Operations. Gross realized gains and losses on available-for-sale debt securities were not material for the nine months ended September 30, 2021 and 2020. The income tax impact allocated to each component of other comprehensive income (loss) was not material for the periods presented.

13. NET INCOME (LOSS) PER SHARE ATTRIBUTABLE TO GILEAD COMMON STOCKHOLDERS

Basic net income (loss) 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 (loss) 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.

Potential shares of common stock excluded from the computation of diluted net income (loss) per share attributable to Gilead common stockholders because their effect would have been antidilutive were 14 million and 15 million for the three and nine months ended September 30, 2021, respectively, and 13 million and 38 million for the three and nine months ended September 30, 2020, respectively.

The following table summarizes the calculation of basic and diluted net income (loss) per share attributable to Gilead common stockholders:

(in millions, except per share amounts)	Three Months Ended September 30, 2021	Three Months Ended September 30, 2020	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020
Net income (loss) attributable to Gilead	$ 2,592	$ 360	$ 5,843	$ (1,428)
Shares used in per share calculation - basic	1,256	1,255	1,256	1,257
Dilutive effect of stock options and equivalents	6	6	6	—
Shares used in per share calculation - diluted	1,262	1,261	1,262	1,257
Net income (loss) per share attributable to Gilead common stockholders - basic	$ 2.06	$ 0.29	$ 4.65	$ (1.14)
Net income (loss) per share attributable to Gilead common stockholders - diluted	$ 2.05	$ 0.29	$ 4.63	$ (1.14)

14. INCOME TAXES

The following table summarizes our income tax expense:

(in millions, except percentages)	Three Months Ended September 30, 2021	Three Months Ended September 30, 2020	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020
Income (loss) before income taxes	$ 3,438	$ 825	$ 7,519	$ (145)
Income tax expense	$ (852)	$ (472)	$ (1,694)	$ (1,310)
Effective tax rate	24.8 %	57.2 %	22.5 %	(903.4)%

Our effective income tax rate of 24.8% for the three months ended September 30, 2021 is 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 is 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 effective income tax rate of 57.2% for the three months ended September 30, 2020 differed from the U.S. federal statutory rate of 21% primarily due to certain acquired IPR&D charges and unfavorable changes in the fair value of our equity investment in Galapagos that are non-deductible for income tax purposes, partially offset by a net discrete tax benefit related to a settlement with a taxing authority.

Our effective income tax rate of (903.4)% for the nine months ended September 30, 2020 differed from the U.S. federal statutory rate of 21% primarily due to a non-deductible $4.5 billion IPR&D charge recorded in connection with our second quarter 2020 acquisition of Forty Seven, in addition to the above mentioned amounts for the three months ended September 30, 2020.

We are currently under examination by the U.S. Internal Revenue Service for the tax years from 2016 to 2018 and by various state and 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 regularly evaluate our exposures associated with our tax filing positions to determine our assessment of unrecognized tax benefits in accordance with the income tax guidance which clarifies the accounting for uncertainty in income taxes.

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

This Quarterly Report on Form 10-Q 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. The forward-looking statements are contained principally in this section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Risk Factors." Words such as "expect," "anticipate," "target," "goal," "project," "hope," "intend," "plan," "believe," "seek," "estimate," "continue," "may," "could," "should," "might," 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, collaboration and licensing arrangements, ongoing litigation and investigation matters, statements regarding the anticipated future impact on our business of the ongoing 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 below under 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 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 the section entitled Risk Factors under Part II, Item 1A 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.

You should read the following management's discussion and analysis of our financial condition and results of operations 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, 2020 and our unaudited Condensed Consolidated Financial Statements for the nine months ended September 30, 2021 and other disclosures (including the disclosures under Part II, Item 1A, "Risk Factors") included in this Quarterly Report on Form 10-Q. Our Condensed Consolidated Financial Statements have been prepared in accordance with U.S. generally accepted accounting principles and are presented in U.S. dollars.

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.

Our portfolio of marketed products includes AmBisome®, Atripla®, Biktarvy®, Cayston®, Complera®/Eviplera®, Descovy®, Descovy for PrEP®, Emtriva®, Epclusa®, Genvoya®, Harvoni®, Hepcludex® (bulevirtide), Hepsera®, Jyseleca®, Letairis®, Odefsey®, Ranexa®, Sovaldi®, Stribild®, Tecartus®, Trodelvy®, Truvada®, Truvada for PrEP®, Tybost®, Veklury®, Vemlidy®, Viread®, Vosevi®, Yescarta® and Zydelig®. The approval status of Hepcludex and Jyseleca vary worldwide, and Hepcludex and Jyseleca are not approved in the United States. We also sell and distribute authorized generic versions of Epclusa and Harvoni in the United States through our separate subsidiary, Asegua Therapeutics, LLC. In addition, we sell and distribute certain products through our corporate partners under collaborative agreements.

Business Highlights[(1)]

Oncology

- In October 2021, we entered into a clinical trial collaboration and supply agreement with Merck & Co., Inc. ("Merck") to evaluate the efficacy of Trodelvy in combination with Merck's anti-PD-1 therapy, Keytruda, as a first-line treatment for patients with locally advanced or metastatic triple-negative breast cancer ("TNBC").
- In October 2021, U.S. Food and Drug Administration ("FDA") approved Tecartus for the treatment of adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia ("ALL"). Tecartus is the first and only CAR T cell therapy approved for adults with ALL.
- In September 2021, Kite Pharma Inc. ("Kite"), a Gilead Company, submitted a supplemental Biologics License Application to FDA for Yescarta to expand its current indication to include the treatment of adults with relapsed or refractory large B-cell lymphoma in the second-line setting.

- In September 2021, Health Canada approved Trodelvy for the treatment of adult patients with unresectable TNBC who have received two or more therapies, at least one of them for metastatic disease. Canada joins Australia, Great Britain, Switzerland and the United States among the countries that have approved Trodelvy for use under Project Orbis, a global collaborative review program for high impact oncology marketing applications across participating countries.
- In August 2021, Kite and Appia Bio, Inc. entered into a collaboration and license agreement to research and develop hematopoietic stem cell derived cell therapies directed toward hematological malignancies.

Viral Diseases

- In October 2021, FDA approved a new low-dose tablet dosage form of Biktarvy for pediatric patients weighing at least 14 kg to less than 25 kg who are virologically suppressed or new to antiretroviral therapy.
- In August 2021, our Marketing Authorization Application for lenacapavir, an investigational, long-acting HIV-1 capsid inhibitor, was fully validated and is now under evaluation with the European Medicines Agency.

(1) We announced and discussed these updates, subsequent to the issuance of our Quarterly Report on Form 10-Q for the second quarter of 2021, in further detail in press releases available on our website at www.gilead.com. Readers are also encouraged to review all other press releases available on our website mentioned above. The content on the referenced websites does not constitute a part of and is not incorporated by reference into this Quarterly Report on Form 10-Q.

Quarterly Financial Highlights

	Three Months Ended September 30,			Nine Months Ended September 30,		
(in millions, except percentages and per share amounts)	**2021**	**2020**	**Change**	**2021**	**2020**	**Change**
Total revenues	$ 7,421	$ 6,577	*13 %*	$ 20,061	$ 17,268	*16 %*
Net income (loss) attributable to Gilead	$ 2,592	$ 360	*NM*	$ 5,843	$ (1,428)	*NM*
Diluted earnings (loss) per share	$ 2.05	$ 0.29	*NM*	$ 4.63	$ (1.14)	*NM*

NM - Not Meaningful

Total revenues increased by 13% to $7.4 billion for the three months ended September 30, 2021, compared to $6.6 billion for the same period in 2020, primarily due to increased sales of Veklury, our FDA-approved treatment for hospitalized patients with the coronavirus disease 2019 (“COVID-19”).

Net income attributable to Gilead was $2.6 billion, or $2.05 diluted earnings per share, for the three months ended September 30, 2021, compared to $360 million, or $0.29 for the same period in 2020. The change was primarily due to lower acquired in-process research and development (“IPR&D”) charges, revenue growth and a decrease in unrealized losses from our equity investments primarily in Galapagos NV (“Galapagos”). Our IPR&D expenses for the three months ended September 30, 2020 were $1.2 billion and related to our collaborations and other investments with Arcus Biosciences, Inc. (“Arcus”), Pionyr Immunotherapeutics, Inc. (“Pionyr”), Tango Therapeutics (“Tango”) and Tizona Therapeutics, Inc. (“Tizona”). Our IPR&D expenses for the three months ended September 30, 2021 were not material.

RESULTS OF OPERATIONS

Total Revenues

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

(in millions, except percentages)	Three Months Ended September 30, 2021	2020	Change	Nine Months Ended September 30, 2021	2020	Change
Product sales:						
HIV	$ 4,189	$ 4,547	*(8)%*	$ 11,777	$ 12,681	*(7)%*
HCV	429	464	*(8)%*	1,488	1,641	*(9)%*
HBV/HDV	247	211	*17 %*	704	616	*14 %*
Veklury	1,923	873	*NM*	4,208	873	*NM*
Cell Therapy	222	147	*51 %*	632	444	*42 %*
Trodelvy	101	—	*NM*	262	—	*NM*
Other	245	251	*(2)%*	777	772	*1 %*
Total product sales	7,356	6,493	*13 %*	19,848	17,027	*17 %*
Royalty, contract and other revenues	65	84	*(23)%*	213	241	*(12)%*
Total revenues	$ 7,421	$ 6,577	*13 %*	$ 20,061	$ 17,268	*16 %*

NM - Not Meaningful

For the three months ended September 30, 2021 compared to the three months ended September 30, 2020

Total Product Sales

Total product sales increased by 13% to $7.4 billion for the three months ended September 30, 2021, compared to $6.5 billion for the same period in 2020, primarily due to increased sales of Veklury. The three months ended September 30, 2021 also reflects the continued growth of Biktarvy and the continued uptake of Trodelvy in the United States and Cell Therapy products in the United States and Europe. We obtained Trodelvy through the fourth quarter 2020 acquisition of Immunomedics, Inc. ("Immunomedics"). The increases were partially offset by lower HIV product sales, as expected, primarily due to the continued generic competition following the October 2020 loss of exclusivity of Truvada and Atripla in the United States.

HIV

HIV product sales decreased by 8% to $4.2 billion for the three months ended September 30, 2021, compared to $4.5 billion for the same period in 2020. The decline was primarily due to the anticipated decline in sales volume of our Truvada (emtricitabine ("FTC") and tenofovir disoproxil fumarate ("TDF"))-based products driven by the continued generic competition following the October 2020 loss of exclusivity of Truvada and Atripla in the United States. Truvada and Atripla product sales were $528 million lower for the three months ended September 30, 2021, compared to the same period in 2020. The decrease was also impacted by lower channel inventory, primarily driven by pandemic-related stocking as compared to the same period in 2020 as well as lower sales of Descovy driven by lower average net selling price and lower sales of Genvoya driven by volume. The decline was partially offset by an increase in Biktarvy product sales driven by higher demand and higher average net selling price. We expect Truvada sales to continue to decline for the remainder of 2021 and beyond as multiple generics are expected to enter the market.

The COVID-19 pandemic continues to impact our HIV business. In the United States, as anticipated, we continued to see a modest recovery in the HIV treatment market volume in the third quarter of 2021; however, it may take several quarters for the U.S. treatment market to return to pre-pandemic levels.

HCV

HCV product sales decreased by 8% to $429 million for the three months ended September 30, 2021, compared to $464 million for the same period in 2020, primarily driven by fewer patient starts due to the impact of the COVID-19 pandemic and lower average net selling price.

Hepatitis B Virus ("HBV") / Hepatitis Delta Virus ("HDV")

HBV and HDV product sales increased by 17% to $247 million for the three months ended September 30, 2021, compared to $211 million for the same period in 2020, primarily due to higher Vemlidy sales volume driven by increased demand primarily in geographies outside the United States. Hepcludex sales were $12 million as launch activities continued across Europe following our first quarter 2021 acquisition of MYR GmbH ("MYR").

Veklury

Veklury product sales were $1.9 billion for the three months ended September 30, 2021, compared to $873 million for the same period in 2020. The increase was primarily due to higher hospital demand consistent with the recent surge in COVID-19 cases. While sales of Veklury are generally affected by, among other things, COVID-19 related rates of infections, hospitalizations and vaccinations, and will continue to be subject to significant volatility and uncertainty, we expect Veklury sales to reduce significantly in the fourth quarter of 2021 as hospitalization rates decline.

Cell Therapy

Cell Therapy product sales increased by 51% to $222 million for the three months ended September 30, 2021, compared to $147 million for the same period in 2020, primarily due to the continued demand of Yescarta for the treatment of relapsed or refractory large B-cell lymphoma and strong uptake in relapsed or refractory indolent follicular lymphoma in the United States and Europe. The increase was also driven by higher Tecartus sales volume for the treatment of mantle cell lymphoma in the United States and Europe.

Trodelvy

Trodelvy product sales were $101 million in the United States and Europe for the three months ended September 30, 2021, following the full FDA approval for second-line metastatic TNBC and accelerated approval for metastatic urothelial cancer both in April 2021.

Other Product Sales

Other product sales, which include AmBisome, Cayston, Jyseleca, Letairis, Ranexa and Zydelig, decreased by 2% to $245 million for the three months ended September 30, 2021, compared to $251 million for the same period in 2020, primarily due to lower Letairis sales, as anticipated, due to continued generic competition following the loss of exclusivity in 2019, partially offset by higher AmBisome sales volume driven by higher demand in geographies outside the United States.

Product Sales by Geographic Area

Of our total product sales, 26% and 22% were generated outside the United States for the three months ended September 30, 2021 and 2020, respectively. 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. Foreign currency exchange, net of hedges, had an immaterial impact on our product sales for the three months ended September 30, 2021, based on a comparison using foreign currency exchange rates from the three months ended September 30, 2020.

Product sales in the United States increased by 8% to $5.5 billion for the three months ended September 30, 2021, compared to $5.1 billion for the same period in 2020, primarily due to increased sales of Veklury as well as the continued growth of Biktarvy, and the continued uptake of Trodelvy and Cell Therapy products. The increases were partially offset by the loss of exclusivity in 2020 of Truvada and Atripla, as expected, and lower sales of Letairis, as anticipated, due to the loss of exclusivity in 2019.

Product sales in Europe increased by 14% to $997 million for the three months ended September 30, 2021, compared to $877 million for the same period in 2020, primarily due to the continued growth of Biktarvy, increased sales of Veklury and higher Cell Therapy sales driven by continued growth of Yescarta and Tecartus.

Product sales in other locations increased by 63% to $880 million for the three months ended September 30, 2021, compared to $540 million for the same period in 2020, primarily due to higher sales volumes of Veklury, AmBisome, Biktarvy and Vemlidy.

For the nine months ended September 30, 2021 compared to the nine months ended September 30, 2020

Total Product Sales

Total product sales increased by 17% to $19.8 billion for the nine months ended September 30, 2021, compared to $17.0 billion for the same period in 2020, primarily due to increased sales of Veklury. The nine months ended September 30, 2021 also reflects the continued growth of Biktarvy in all geographies and the continued uptake of Trodelvy and Cell Therapy and HBV/HDV products. The increases were partially offset by a decline in HIV product sales, as well as lower HCV product sales driven by fewer patient starts. The decrease in HIV product sales, as expected, was primarily due to the continued generic competition following the October 2020 loss of exclusivity of Truvada and Atripla in the United States.

HIV

HIV product sales decreased by 7% to $11.8 billion for the nine months ended September 30, 2021, compared to $12.7 billion for the same period in 2020, primarily due to the anticipated decline in sales volume of our Truvada (FTC/TDF)-based products driven by the continued generic competition following the October 2020 loss of exclusivity of Truvada and Atripla in the United States. Truvada and Atripla product sales were $1.2 billion lower for the nine months ended September 30, 2021, compared to the same period in 2020. The decrease was also impacted by lower sales of Descovy driven by lower average net selling price and lower sales of Genvoya driven by volume. The decline was partially offset by an increase in Biktarvy product sales driven by higher demand.

HCV

HCV product sales decreased by 9% to $1.5 billion for the nine months ended September 30, 2021, compared to $1.6 billion for the same period in 2020, primarily due to fewer patient starts.

HBV/HDV

HBV and HDV product sales increased by 14% to $704 million for the nine months ended September 30, 2021, compared to $616 million for the same period in 2020, primarily due to higher Vemlidy sales volume. The nine months ended September 30, 2021 also reflects $25 million of Hepcludex sales following the completion of our first quarter 2021 acquisition of MYR.

Veklury

Veklury product sales were $4.2 billion for the nine months ended September 30, 2021, compared to $873 million for the same period in 2020. The increase was primarily due to higher hospital demand. Veklury became commercially available in the third quarter of 2020 resulting in partial year sales for the nine months ended September 30, 2020.

Cell Therapy

Cell Therapy product sales increased by 42% to $632 million for the nine months ended September 30, 2021, compared to $444 million for the same period in 2020, primarily due to higher sales volume of Yescarta and Tecartus in the United States and Europe.

Trodelvy

Trodelvy product sales were $262 million in the United States and Europe for the nine months ended September 30, 2021, following the completion of our fourth quarter 2020 acquisition of Immunomedics.

Other Product Sales

Other product sales, which include AmBisome, Cayston, Jyseleca, Letairis, Ranexa and Zydelig, increased by 1% to $777 million for the nine months ended September 30, 2021, compared to $772 million for the same period in 2020. The increase was primarily due to higher AmBisome sales volume driven by higher demand in geographies outside the United States, partially offset by lower Letairis sales, as anticipated, due to continued generic competition following the loss of exclusivity in 2019.

Product Sales by Geographic Area

Of our total product sales, 30% and 25% were generated outside the United States for the nine months ended September 30, 2021 and 2020, respectively. 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. Foreign currency exchange, net of hedges, had a favorable impact on our product sales of $160 million for the nine months ended September 30, 2021, based on a comparison using foreign currency exchange rates from the nine months ended September 30, 2020.

Product sales in the United States increased by 9% to $13.9 billion for the nine months ended September 30, 2021, compared to $12.8 billion for the same period in 2020, primarily due to increased sales of Veklury, the growth of Biktarvy, the continued uptake of Trodelvy, and the continued growth of Cell Therapy products. The increases were partially offset by the loss of exclusivity of Truvada and Atripla, as expected, the anticipated decline in sales volume of Letairis following the loss of exclusivity in 2019 and lower HCV sales driven by lower demand.

Product sales in Europe increased by 35% to $3.4 billion for the nine months ended September 30, 2021, compared to $2.5 billion for the same period in 2020, primarily due to increased sales of Veklury, the continued growth of Biktarvy, higher AmBisome sales driven by higher demand, and the continued growth of Cell Therapy products. HCV sales volume decreased due to the impact of the COVID-19 pandemic, partially offset by a favorable government rebate adjustment. Foreign currency exchange, net of hedges, had a favorable impact on our Europe product sales of $101 million for the nine months ended September 30, 2021, based on a comparison using foreign currency exchange rates from the nine months ended September 30, 2020.

Product sales in other locations increased by 50% to $2.5 billion for the nine months ended September 30, 2021, compared to $1.7 billion for the same period in 2020, primarily due to higher sales volumes of Veklury, Biktarvy, Vemlidy and AmBisome, partially offset by lower HCV sales volume.

The following table summarizes the period-over-period changes in our product sales:

	Three Months Ended September 30,			Nine Months Ended September 30,		
(in millions, except percentages)	**2021**	**2020**	**Change**	**2021**	**2020**	**Change**
HIV Products						
Descovy (FTC/TAF) Based Products						
Biktarvy – U.S.	$ 1,875	$ 1,584	*18 %*	$ 4,926	$ 4,346	*13 %*
Biktarvy – Europe	254	194	*31 %*	707	528	*34 %*
Biktarvy – Other International	147	113	*30 %*	461	314	*47 %*
	2,276	1,891	*20 %*	6,094	5,188	*17 %*
Descovy – U.S.	355	424	*(16)%*	994	1,124	*(12)%*
Descovy – Europe	42	49	*(14)%*	128	156	*(18)%*
Descovy – Other International	36	35	*3 %*	105	103	*2 %*
	433	508	*(15)%*	1,227	1,383	*(11)%*
Genvoya – U.S.	576	669	*(14)%*	1,633	1,927	*(15)%*
Genvoya – Europe	100	116	*(14)%*	306	376	*(19)%*
Genvoya – Other International	68	61	*11 %*	184	183	*1 %*
	744	846	*(12)%*	2,123	2,486	*(15)%*
Odefsey – U.S.	275	309	*(11)%*	773	851	*(9)%*
Odefsey – Europe	112	116	*(3)%*	336	341	*(1)%*
Odefsey – Other International	12	12	*— %*	39	36	*8 %*
	399	437	*(9)%*	1,148	1,228	*(7)%*
Revenue share – Symtuza[(1)] – U.S.	86	82	*5 %*	261	244	*7 %*
Revenue share – Symtuza[(1)] – Europe	41	34	*21 %*	125	112	*12 %*
Revenue share – Symtuza[(1)] – Other International	3	2	*50 %*	8	6	*33 %*
	130	118	*10 %*	394	362	*9 %*
Total Descovy (FTC/TAF) Based Products – U.S.	3,167	3,068	*3 %*	8,587	8,492	*1 %*
Total Descovy (FTC/TAF) Based Products – Europe	549	509	*8 %*	1,602	1,513	*6 %*
Total Descovy (FTC/TAF) Based Products – Other International	266	223	*19 %*	797	642	*24 %*
	3,982	3,800	*5 %*	10,986	10,647	*3 %*
Truvada (FTC/TDF) Based Products						
Atripla – U.S.	21	99	*(79)%*	96	275	*(65)%*
Atripla – Europe	2	5	*(60)%*	10	17	*(41)%*
Atripla – Other International	4	9	*(56)%*	12	19	*(37)%*
	27	113	*(76)%*	118	311	*(62)%*
Complera / Eviplera – U.S.	28	26	*8 %*	73	77	*(5)%*
Complera / Eviplera – Europe	31	35	*(11)%*	104	124	*(16)%*
Complera / Eviplera – Other International	5	9	*(44)%*	12	17	*(29)%*
	64	70	*(9)%*	189	218	*(13)%*
Stribild – U.S.	28	27	*4 %*	94	100	*(6)%*
Stribild – Europe	11	13	*(15)%*	33	42	*(21)%*
Stribild – Other International	3	2	*50 %*	12	12	*— %*
	42	42	*— %*	139	154	*(10)%*
Truvada – U.S.	55	492	*(89)%*	268	1,245	*(78)%*
Truvada – Europe	5	6	*(17)%*	18	20	*(10)%*
Truvada – Other International	7	11	*(36)%*	24	37	*(35)%*
	67	509	*(87)%*	310	1,302	*(76)%*

Total Truvada (FTC/TDF) Based Products – U.S.	132	644	*(80)%*	531	1,697	*(69)%*
Total Truvada (FTC/TDF) Based Products – Europe	49	59	*(17)%*	165	203	*(19)%*
Total Truvada (FTC/TDF) Based Products – Other International	19	31	*(39)%*	60	85	*(29)%*
	200	734	*(73)%*	756	1,985	*(62)%*
Other HIV[(2)] – U.S.	3	10	*(70)%*	14	24	*(42)%*
Other HIV[(2)] – Europe	4	1	*NM*	9	4	*NM*
Other HIV[(2)] – Other International	—	2	*(100)%*	12	21	*(43)%*
	7	13	*(46)%*	35	49	*(29)%*
Total HIV – U.S.	3,302	3,722	*(11)%*	9,132	10,213	*(11)%*
Total HIV – Europe	602	569	*6 %*	1,776	1,720	*3 %*
Total HIV – Other International	285	256	*11 %*	869	748	*16 %*
	4,189	4,547	*(8)%*	11,777	12,681	*(7)%*
HCV Products						
Ledipasvir / Sofosbuvir[(3)] – U.S.	14	36	*(61)%*	63	113	*(44)%*
Ledipasvir / Sofosbuvir[(3)] – Europe	5	11	*(55)%*	24	26	*(8)%*
Ledipasvir / Sofosbuvir[(3)] – Other International	26	37	*(30)%*	76	124	*(39)%*
	45	84	*(46)%*	163	263	*(38)%*
Sofosbuvir / Velpatasvir[(4)] – U.S.	173	170	*2 %*	649	646	*— %*
Sofosbuvir / Velpatasvir[(4)] – Europe	77	74	*4 %*	234	253	*(8)%*
Sofosbuvir / Velpatasvir[(4)] – Other International	82	86	*(5)%*	272	330	*(18)%*
	332	330	*1 %*	1,155	1,229	*(6)%*
Other HCV[(5)] – U.S.	37	35	*6 %*	97	100	*(3)%*
Other HCV[(5)] – Europe	12	13	*(8)%*	64	37	*73 %*
Other HCV[(5)] – Other International	3	2	*50 %*	9	12	*(25)%*
	52	50	*4 %*	170	149	*14 %*
Total HCV – U.S.	224	241	*(7)%*	809	859	*(6)%*
Total HCV – Europe	94	98	*(4)%*	322	316	*2 %*
Total HCV – Other International	111	125	*(11)%*	357	466	*(23)%*
	429	464	*(8)%*	1,488	1,641	*(9)%*
HBV/HDV Products						
Vemlidy – U.S.	103	99	*4 %*	266	248	*7 %*
Vemlidy – Europe	9	8	*13 %*	25	22	*14 %*
Vemlidy – Other International	96	70	*37 %*	298	194	*54 %*
	208	177	*18 %*	589	464	*27 %*
Viread – U.S.	1	3	*(67)%*	8	10	*(20)%*
Viread – Europe	7	8	*(13)%*	22	27	*(19)%*
Viread – Other International	18	21	*(14)%*	55	100	*(45)%*
	26	32	*(19)%*	85	137	*(38)%*
Other HBV/HDV[(6)] – U.S.	—	—	*NM*	1	9	*(89)%*
Other HBV/HDV[(6)] – Europe	13	2	*NM*	29	6	*NM*
	13	2	*NM*	30	15	*NM*
Total HBV/HDV – U.S.	104	102	*2 %*	275	267	*3 %*
Total HBV/HDV – Europe	29	18	*61 %*	76	55	*38 %*
Total HBV/HDV – Other International	114	91	*25 %*	353	294	*20 %*
	247	211	*17 %*	704	616	*14 %*
Veklury						
Veklury – U.S.	1,527	785	*95 %*	2,763	785	*NM*
Veklury – Europe	109	60	*82 %*	761	60	*NM*
Veklury – Other International	287	28	*NM*	684	28	*NM*
	1,923	873	*NM*	4,208	873	*NM*

Cell Therapy Products						
Tecartus – U.S.	35	5	*NM*	94	5	*NM*
Tecartus – Europe	12	4	*NM*	25	5	*NM*
	47	9	*NM*	119	10	*NM*
Yescarta – U.S.	100	85	*18 %*	300	283	*6 %*
Yescarta – Europe	66	51	*29 %*	188	144	*31 %*
Yescarta – Other International	9	2	*NM*	25	7	*NM*
	175	138	*27 %*	513	434	*18 %*
Total Cell Therapy – U.S.	135	90	*50 %*	394	288	*37 %*
Total Cell Therapy – Europe	78	55	*42 %*	213	149	*43 %*
Total Cell Therapy – Other International	9	2	*NM*	25	7	*NM*
	222	147	*51 %*	632	444	*42 %*
Trodelvy						
Trodelvy – U.S.	100	—	*NM*	261	—	*NM*
Trodelvy– Europe	1	—	*NM*	1	—	*NM*
	101	—	*NM*	262	—	*NM*
Other Products						
AmBisome – U.S.	7	18	*(61)%*	32	46	*(30)%*
AmBisome – Europe	67	58	*16 %*	202	166	*22 %*
AmBisome – Other International	69	35	*97 %*	186	113	*65 %*
	143	111	*29 %*	420	325	*29 %*
Letairis – U.S.	46	78	*(41)%*	157	241	*(35)%*
Ranexa – U.S.	—	—	*NM*	5	9	*(44)%*
Zydelig – U.S.	6	8	*(25)%*	22	24	*(8)%*
Zydelig – Europe	7	9	*(22)%*	27	30	*(10)%*
Zydelig – Other International	—	—	*NM*	1	1	*— %*
	13	17	*(24)%*	50	55	*(9)%*
Other[7] – U.S.	28	32	*(13)%*	82	103	*(20)%*
Other[7] – Europe	10	10	*— %*	41	32	*28 %*
Other[7] – Other International	5	3	*67 %*	22	7	*NM*
	43	45	*(4)%*	145	142	*2 %*
Total Other – U.S.	87	136	*(36)%*	298	423	*(30)%*
Total Other – Europe	84	77	*9 %*	270	228	*18 %*
Total Other – Other International	74	38	*95 %*	209	121	*73 %*
	245	251	*(2)%*	777	772	*1 %*
Total product sales – U.S.	5,479	5,076	*8 %*	13,932	12,835	*9 %*
Total product sales – Europe	997	877	*14 %*	3,419	2,528	*35 %*
Total product sales – Other International	880	540	*63 %*	2,497	1,664	*50 %*
	$ 7,356	$ 6,493	*13 %*	$ 19,848	$ 17,027	*17 %*

NM - Not Meaningful

(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.

(2) Includes 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 and Jyseleca.

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, 2021	2020	Change	Nine Months Ended September 30, 2021	2020	Change
Cost of goods sold	$ 1,223	$ 1,141	*7 %*	$ 3,974	$ 3,174	*25 %*
Product gross margin	*83.4 %*	*82.4 %*	*100 bps*	*80.0 %*	*81.4 %*	*-140 bps*
Research and development ("R&D") expenses	$ 1,147	$ 1,158	*(1)%*	$ 3,336	$ 3,461	*(4)%*
Acquired IPR&D expenses	$ 19	$ 1,171	*(98)%*	$ 177	$ 5,792	*(97)%*
Selling, general and administrative ("SG&A") expenses	$ 1,190	$ 1,106	*8 %*	$ 3,596	$ 3,421	*5 %*

Cost of Goods Sold and Product Gross Margin

Cost of goods sold for the three and nine months ended September 30, 2021 increased by $82 million and $800 million, or 7% and 25%, respectively, compared to the same periods in 2020, primarily due to higher acquisition-related expenses from amortization of finite-lived intangible assets and inventory step-up charges driven by our acquisitions of Immunomedics and MYR, as well as higher product sales and inventory reserves. The increases were partially offset by the reversal of a previously recorded $175 million litigation reserve following a favorable court decision and a decrease in royalty expenses primarily due to lower sales of products containing emtricitabine and elvitegravir.

Product gross margin for the three months ended September 30, 2021, compared to the same period in 2020, increased primarily due to the reversal of the aforementioned previously recorded litigation reserve following a favorable court decision, lower royalty expenses and change in product mix, partially offset by higher amortization expense of finite-lived intangible assets.

Product gross margin for the nine months ended September 30, 2021, compared to the same period in 2020, decreased primarily due to higher amortization expense of finite-lived intangible assets, partially offset by lower royalty expenses.

Research and Development Expenses

R&D expenses consist primarily of clinical studies performed by contract research organizations, materials and supplies, payments related to collaborative and other arrangements including milestone payments, licenses and fees, expense reimbursements to the collaboration partners, personnel costs including salaries, benefits and stock-based compensation expense, and overhead allocations including various support and infrastructure costs.

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

The following table provides a period-over-period breakout of our R&D expenses by major cost type:

(in millions, except percentages)	Three Months Ended September 30, 2021	2020	Change	Nine Months Ended September 30, 2021	2020	Change
Clinical studies and outside services	$ 538	$ 532	*1 %*	$ 1,241	$ 1,517	*(18)%*
Personnel, infrastructure and other expenses	533	547	*(3)%*	1,880	1,615	*16 %*
Stock-based compensation expenses	76	79	*(4)%*	215	329	*(35)%*
Total	$ 1,147	$ 1,158	*(1)%*	$ 3,336	$ 3,461	*(4)%*

R&D expenses for the three and nine months ended September 30, 2021 decreased by 1% and 4%, respectively, compared to the same periods in 2020, primarily due to lower expenses largely driven by wind-down or completion of certain remdesivir and inflammation related clinical programs, partially offset by higher investments in Trodelvy and magrolimab clinical activities. R&D expenses for the nine months ended September 30, 2020 included stock-based compensation expense related to our second quarter 2020 acquisition of Forty Seven, Inc. ("Forty Seven").

Acquired In-Process Research and Development Expenses

Acquired IPR&D expenses reflect IPR&D impairments as well as the initial costs of externally developed IPR&D projects, acquired directly in a transaction other than a business combination, that do not have an alternative future use, including upfront and other payments related to various collaborations and the initial costs of rights to IPR&D projects. IPR&D assets capitalized are tested for impairment in the fourth quarter of each year, or earlier if impairment indicators exist. No IPR&D impairment charges were recorded during the three and nine months ended September 30, 2021 and 2020.

Acquired IPR&D expenses of $19 million and $177 million for the three and nine months ended September 30, 2021, respectively, were related to licensing, collaboration, investment and other arrangements we entered into during the periods. Acquired IPR&D expenses of $1.2 billion for the three months ended September 30, 2020 included charges related to our collaborations and other investments we entered into during the quarter with Arcus, Pionyr, Tango and Tizona. Acquired IPR&D expenses of $5.8 billion for the nine months ended September 30, 2020 also included a $4.5 billion charge recorded in connection with the second quarter 2020 acquisition of Forty Seven.

Selling, General and Administrative Expenses

SG&A expenses relate to sales and marketing, finance, human resources, legal and other administrative activities, including information technology investments. Expenses consist primarily of personnel costs, facilities and overhead costs, outside marketing, advertising and legal expenses and other general and administrative costs. SG&A expenses also include the branded prescription drug fee.

SG&A expenses for the three months ended September 30, 2021 increased by $84 million or 8%, compared to the same period in 2020, primarily due to higher promotional and marketing activities across all geographies, partially offset by lower commercial activities in inflammation.

SG&A expenses for the nine months ended September 30, 2021, increased by $175 million or 5%, compared to the same period in 2020, primarily due to an expense of $212 million related to the donation of certain equity securities at fair value to the Gilead Foundation, a California nonprofit organization (the "Foundation"), during the second quarter of 2021. SG&A expenses for nine months ended September 30, 2020 included a second quarter 2020 charge of $97 million related to a Department of Justice investigation, which settled in the third quarter of 2020.

Other Income (Expense), Net and Interest Expense

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
(in millions, except percentages)	**2021**	**2020**	**Change**	**2021**	**2020**	**Change**
Other income (expense), net	$ (154)	$ (940)	*(84)%*	$ (696)	$ (848)	*(18)%*
Interest expense	$ (250)	$ (236)	*6 %*	$ (763)	$ (717)	*6 %*

The changes in Other income (expense), net for the three and nine months ended September 30, 2021, compared to the same periods in 2020, primarily reflect a decrease in unrealized losses from fair value adjustments of our investments in equity securities largely driven by our investment in Galapagos, partially offset by lower interest income.

Interest expense for the three and nine months ended September 30, 2021 increased by $14 million and $46 million, or 6% and 6%, respectively, compared to the same periods in 2020, primarily due to an increase in borrowing related to the fourth quarter 2020 acquisition of Immunomedics, partially offset by favorable effects from debt maturities and repayments.

Income Taxes

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
(in millions, except percentages)	**2021**	**2020**	**Change**	**2021**	**2020**	**Change**
Income (loss) before income taxes	$ 3,438	$ 825	*$ 2,613*	$ 7,519	$ (145)	*$ 7,664*
Income tax expense	$ (852)	$ (472)	*$ 380*	$ (1,694)	$ (1,310)	*$ 384*
Effective tax rate	24.8 %	57.2 %	*NM*	22.5 %	(903.4)%	*NM*

NM - Not Meaningful

Our effective tax rate and provision differed for the three months ended September 30, 2021, compared to the same period in 2020, primarily due to certain acquired IPR&D charges and unfavorable changes in the fair value of our equity investment in Galapagos that are non-deductible for income tax purposes, recorded in the three months ended September 30, 2020.

Our effective tax rate and provision differed for the nine months ended September 30, 2021, compared to the same period in 2020, primarily due to a non-deductible $4.5 billion IPR&D charge recorded in connection with our second quarter 2020 acquisition of Forty Seven, in addition to the above mentioned amounts for the three months ended September 30, 2020.

LIQUIDITY AND CAPITAL RESOURCES

We believe that our existing capital resources, supplemented by our cash flows generated from operating activities, will be adequate to satisfy our capital needs for the foreseeable future.

The following table summarizes our cash, cash equivalents and marketable debt securities and working capital:

(in millions)	September 30, 2021	December 31, 2020
Cash, cash equivalents and marketable debt securities	$ 6,837	$ 7,910
Working capital	$ 3,746	$ 4,599

Cash, Cash Equivalents and Marketable Debt Securities

Cash, cash equivalents and marketable debt securities as of September 30, 2021 decreased by $1.1 billion, or 14%, compared to December 31, 2020. During the nine months ended September 30, 2021, we generated $8.2 billion in operating cash flow, made debt repayments of $3.75 billion, utilized $1.2 billion for our first quarter 2021 acquisition of MYR, paid cash dividends of $2.7 billion, utilized $497 million on open market repurchases of our common stock and had additional investing cash outlays of approximately $1.1 billion.

Working Capital

Working capital, which is current assets less current liabilities, decreased by $853 million, or 19%, compared to December 31, 2020, primarily due to the utilization of cash, cash equivalents and marketable debt securities and other activities as noted above.

Accounts receivable decreased by $326 million, compared to December 31, 2020, primarily due to collections of Veklury receivables during the nine months ended September 30, 2021.

Accrued and other current liabilities decreased by $555 million compared to December 31, 2020, primarily reflecting the timing of accruals and payments, as well as estimated and transition tax payments made to taxing authorities during the nine months ended September 30, 2021.

Cash Flows

The following table summarizes our cash flow activities:

	Nine Months Ended September 30,	
(in millions)	2021	2020
Cash provided by (used in):		
Operating activities	$ 8,179	$ 6,252
Investing activities	$ (2,853)	$ (5,638)
Financing activities	$ (6,935)	$ 639

Operating Activities

Cash provided by operating activities represents the cash receipts and disbursements related to all activities other than investing and financing activities. Operating cash flow is derived by adjusting our net income for non-cash items and changes in operating assets and liabilities. Cash provided by operating activities increased by $1.9 billion to $8.2 billion for the nine months ended September 30, 2021, compared to the same period in 2020. The increase was primarily due to revenue growth from sales of Veklury as well as higher collections of receivables during the nine months ended September 30, 2021.

Investing Activities

Cash used in investing activities primarily consists of purchases, sales and maturities of our marketable debt securities, capital expenditures, acquisitions, including IPR&D, net of cash acquired, purchases of equity securities and other investments. Cash used in investing activities decreased by $2.8 billion to $2.9 billion for the nine months ended September 30, 2021, compared to the same period in 2020. The change in cash used in investing activities was primarily due to $1.2 billion of payments made for our first quarter 2021 acquisition of MYR, compared to $4.7 billion of payments made for our second quarter 2020 acquisition of Forty Seven.

Financing Activities

Cash used in financing activities for the nine months ended September 30, 2021 was $6.9 billion, compared to cash provided by financing activities of $639 million for the same period in 2020. During the nine months ended September 30, 2021, we utilized cash for $3.8 billion debt repayments, $2.7 billion dividend payments and $497 million common stock repurchases. During the nine months ended September 30, 2020, we obtained $7.2 billion in proceeds from the September 2020 senior unsecured notes offering, net of issuance costs, in anticipation of our fourth quarter 2020 Immunomedics acquisition, partially offset by cash utilized for $2.6 billion dividend payments, $2.5 billion debt repayments and $1.6 billion common stock repurchases. In October 2021, the Board of Directors declared a quarterly dividend of $0.71 per share of common stock, which is payable in December 2021. Future dividends will be subject to Board approval.

Debt and Credit Facilities

A summary of our borrowings under various financing arrangements is included in Note 10. Debt and Credit Facilities of the Notes to Condensed Consolidated Financial Statements included in Part I, Item I 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.

During the nine months ended September 30, 2021, we repaid $3.75 billion of debt. We repaid $1.0 billion of senior unsecured notes due April 2021 in the first quarter of 2021 and $1.25 billion of senior unsecured notes due December 2021 in the third quarter of 2021. Additionally, we repaid $1.0 billion principal amount outstanding under our three-year $1.0 billion senior unsecured term loan facility due October 2023 and $500 million of our senior unsecured floating rate notes due September 2021 upon maturity. In October 2021, we exercised our option to call $500 million of our floating rate senior unsecured notes and $500 million of our 0.75% senior unsecured notes, both having a final maturity of September 2023. The notes will be repaid in November 2021.

No new debt was issued during the three and nine months ended September 30, 2021. We are required to comply with certain covenants under our note indentures governing our senior unsecured notes. As of September 30, 2021, we were in compliance with all covenants.

CRITICAL ACCOUNTING POLICIES, ESTIMATES AND JUDGMENTS

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, such as the economic considerations related to the impact that the ongoing COVID-19 pandemic could have on our significant accounting estimates. 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, 2020. There were no material changes to our critical accounting policies and estimates during the nine months ended September 30, 2021.

OFF-BALANCE SHEET ARRANGEMENTS

We do not have any off-balance sheet arrangements as defined in Item 303(a)(4)(ii) of Regulation S-K.

RECENT ACCOUNTING PRONOUNCEMENTS

There have been no new accounting pronouncements issued nor adopted during the nine months ended September 30, 2021 that are of significance to us.

ACQUISITIONS, COLLABORATIONS AND OTHER ARRANGEMENTS

See Note 6. Acquisitions and Note 9. Collaborations and Other Arrangements of the Notes to Condensed Consolidated Financial Statements included in Part I, Item I of this Quarterly Report on Form 10-Q for additional information.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

There have been no material changes in our market risk during the three and nine months ended September 30, 2021 compared to the disclosures in Part II, Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2020.

Item 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

An evaluation as of September 30, 2021 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 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, 2021.

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, 2021, 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 11. Commitments and Contingencies of the Notes to Condensed Consolidated Financial Statements included in Part I, Item I 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 Products

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, 2021, sales of our HIV products accounted for approximately 59% 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, most of our HIV products contain tenofovir alafenamide ("TAF"), tenofovir disoproxil fumarate ("TDF") and/or emtricitabine ("FTC"), which belong 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 hospitalized patients with COVID-19. While the utilization of Veklury has largely tracked rates of COVID-19 infections, hospitalizations and vaccinations, 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 potential for new and better therapeutics, the availability, uptake and effectiveness of vaccines, fluctuating hospital utilization rates and the emergence of new variants. If we are unable to accurately forecast demand or manufacture Veklury at levels to meet actual demand, then this may result in shortages or excess inventory that may be written off. We also remain subject to significant public attention and scrutiny over the complex decisions made regarding the clinical data, allocation, distribution and pricing of Veklury, all of which affects our corporate reputation.

Cell Therapy

Advancing a novel and personalized therapy such as Yescarta or Tecartus, which are Chimeric Antigen Receptor ("CAR") T cell therapies, creates significant challenges, including:

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

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

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

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. 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, 2021, approximately 92% 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, private insurers and government payers often reduce the amount they will reimburse patients for these products, which increases pressure on us to reduce 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. In addition, in November 2020, the Centers for Medicare & Medicaid Services (“CMS”) issued an interim final rule that would substantially alter the Medicare Part B reimbursement system for physician-administered medicines as of January 1, 2021. This rule is subject to ongoing litigation and CMS has been preliminarily enjoined from implementing the rule. 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 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 bills has dramatically increased in recent years. For example, Congress has proposed bills to require the Department of Health and Human Services to negotiate prices for certain drugs, change the Medicare Part B and D benefit to impose an inflation-based rebate when list prices for drugs grow faster than inflation, increase manufacturer contributions in some or all of the Medicare Part D benefit phases and require manufacturer refunds on discarded drug from single-use vials. 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. Such initiatives and 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 European Union member states, have established complex and lengthy procedures to obtain price approvals, coverage reimbursement and periodically review their pricing and reimbursement decisions. The outcome of this review cannot be predicted and could have an adverse effect on the pricing and reimbursement of our medicinal products in the European Union member states. Reductions in the pricing of our medicinal 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, in December 2020, CMS issued a final rule that will make certain changes to the calculation of rebates under the Medicaid Drug Rebate Program. Among other changes, effective January 1, 2023, the final rule will change the requirements for excluding manufacturer co-pay coupons from the Medicaid “best price.” These changes are subject to ongoing litigation. If these changes go into effect, they could substantially increase our Medicaid rebate obligations and decrease the prices we charge 340B covered entities. The continued growth of the 340B program also limits the prices we may charge on an increasing percentage of sales.

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 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 European Union, there are barriers to reimbursement in individual countries that could limit the uptake of Yescarta and Tecartus.

In addition, 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 imports from countries where our products are available at lower prices or the unlawful distribution of generic 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 allows 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 European Union, we are required to permit products purchased in one European Union member state to be sold in another member state. Purchases of our products in countries where our selling prices are relatively low for resale in countries 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 "Buyers Clubs" around the world that promote the personal importation of our products and generic versions of our products that have not been approved for use in the countries into which they are imported. 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 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. Illegally diverted and counterfeit medicines pose a serious risk to patient health and safety and may raise the risk of product recalls. 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 not successful, which may adversely affect our 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 products that we develop for each intended use through extensive preclinical studies and clinical trials. The results from preclinical and early clinical 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. If any of our product candidates fails to achieve its primary endpoint in clinical trials, if safety issues arise or if the results from our clinical trials are otherwise inadequate to support regulatory approval of our product candidates, commercialization of that product candidate could be delayed or halted. In addition, we may also face challenges in clinical trial protocol design.

We may be adversely impacted if the clinical trials for any of the product candidates in our pipeline are delayed or terminated. We face numerous risks and uncertainties with our product candidates that could prevent completion of development of these product candidates. These risks include our ability to enroll patients in clinical trials, the possibility of unfavorable results of our clinical trials, the need to modify or delay our clinical trials or to perform additional trials and the risk of failing to obtain FDA and other regulatory agency approvals. As a result, our product candidates may never be successfully commercialized. 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. We may be adversely impacted if we do not have favorable results from clinical studies and other programs in our pipeline cannot be completed on a timely basis or at all. In addition, clinical trials involving our commercial products could raise new safety issues for our existing products.

In addition, 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 may also need to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications and quality standards, 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 sufficient quantities 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 were 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 health care industry.

The health care industry is subject to various federal, state and international laws and regulations pertaining to drug reimbursement, rebates, price reporting, health care 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, the Medicaid Rebate Statute, 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 health care 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, Note 11. Commitments and Contingencies of the Notes to Condensed Consolidated Financial Statements included in Part I, Item I 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 subsequent to 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 patients 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.

Since patent applications are confidential for a period of time before a patent is issued, we may not know if our competitors 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 11. Commitments and Contingencies of the Notes to Condensed Consolidated Financial Statements included in Part I, Item I of this Quarterly Report on Form 10-Q. 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.

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 bictegravir, as well as certain uses of combinations of FTC and TDF or TAF. For example, in February 2018, ViiV Healthcare Company ("ViiV") filed a lawsuit against us in the U.S. District Court of Delaware, alleging that the commercialization of bictegravir, sold commercially in combination with TAF and FTC as Biktarvy, infringes on ViiV's U.S. Patent No. 8,129,385 (the "'385 patent"), covering ViiV's dolutegravir. Bictegravir is structurally different from dolutegravir, and we believe that bictegravir does not infringe the claims of the '385 patent. The court has set a trial date of January 2022 for this lawsuit. ViiV is seeking billions of dollars for alleged damages comprised of ViiV's lost profits and a royalty on sales of bictegravir from launch through the trial. In addition, should a court find that we are liable for infringement, we expect ViiV will seek a royalty on sales after the trial. ViiV calculates these damages based on the cumulative U.S. revenues from Biktarvy since launch, which have totaled $16.4 billion through September 30, 2021. Although we cannot predict with certainty the ultimate outcome of this litigation, an adverse judgment could result in substantial monetary damages, including ViiV's lost profits and royalties through trial, and a going-forward royalty stream on future sales. See a description of our litigation related to these and other matters in Note 11. Commitments and Contingencies of the Notes to Condensed Consolidated Financial Statements included in Part I, Item I 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, including ongoing litigation with ViiV related to bictegravir in which ViiV is seeking billions of dollars of alleged damages in a trial scheduled to begin in January 2022. These matters could require us to pay significant monetary damages, including royalty payments for past and future sales. We expect these matters will continue to require a high level of internal and financial resources for the foreseeable future. These matters have reduced, and are expected to continue to reduce, our earnings and require significant management attention.

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

For a description of our litigation, investigation and other dispute-related matters, see Note 11. Commitments and Contingencies of the Notes to Condensed Consolidated Financial Statements included in Part I, Item I 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 outbreak.

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. In addition to the developments discussed in Part I, Item 2 “Management's Discussion and Analysis of Financial Condition and Results of Operations,” 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: This 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.
- Regulatory Reviews: The operations of FDA, EMA or other regulatory agencies may be adversely affected. We may also experience delays in necessary interactions with regulatory authorities around the world, including with respect to any anticipated filing, which together with other factors resulting from the pandemic may adversely impact our ability to launch new commercial products.
- 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 HIV treatment and prevention and hepatitis C virus (“HCV”) treatment. For example, we have seen a reduction in prescription refills for HIV treatment and prevention as a result of higher discontinuations. We have also observed lower levels of screening and diagnosis for HIV, resulting in fewer treatment initiations. In addition, with increased levels of unemployment during the course of the pandemic, we have experienced a shift 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. 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. On-site employees testing positive for COVID-19 could lead to mandatory quarantines and potential site shutdowns.

- Financial: The pandemic has had, and may continue to have, an adverse financial impact in the short-term and potentially beyond. In particular, our HIV treatment and HCV businesses have been and continue to be adversely impacted. For example, we observed a reduction in the overall U.S. HIV treatment volume in the second half of 2020 and the first quarter of 2021, and it is uncertain when treatment volume will return to pre-pandemic levels. In HCV, patient starts have also remained below pre-pandemic levels. 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, 2021, approximately 30% 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 may be adversely impacted if the U.S. dollar appreciates significantly against certain currencies and our hedging program does not sufficiently offset the effects of such appreciation.
- 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 be uninsured or inadequately insured. 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 adequate 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. For example, on January 31, 2020, the United Kingdom withdrew from the European Union, which initiated a renegotiation of the United Kingdom and the European Union's future relationship. There continues to be uncertainty concerning any changes in the laws and regulations governing the conduct of clinical trials and marketing of medicinal products in the United Kingdom following the country's exit from the European Union. This uncertainty may lead to significant complexity and risks for our company and our ability to research, develop and market medicinal products in the European Union and the United Kingdom.

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, our processes and controls may not always comply with evolving standards for identifying, measuring and reporting ESG metrics, 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.

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 acquiror 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 Symtuza. 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.

We are dependent on information technology systems, infrastructure and data, which may be subject to cyberattacks, security breaches and legal claims.

We are dependent upon information technology systems, infrastructure and data, including our Kite Konnect 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 pose a risk that sensitive data, including our intellectual property or trade secrets or the personal information of our employees, patients, customers or other business partners may be exposed to unauthorized persons or to the public. Cyberattacks are increasing in their frequency, sophistication and intensity, including during the pandemic. Cyberattacks 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. There can be no assurance that our efforts, or the efforts of our partners and vendors, to invest in the protection of information technology infrastructure and data will prevent future service interruptions or identify breaches in our systems. Such interruptions or breaches could cause the loss of critical or sensitive information, including personal information. In addition, our insurance may not be sufficient in type or amount to cover the losses that may result from an interruption or breach of our systems.

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”) that became effective in Europe in 2018 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 (“CCPA”) that became effective in January 2020, and the California Privacy Rights Act (the “CPRA”) that was approved by voters in November 2020, and others that may be passed, similarly introduce requirements with respect to personal information, and non-compliance with CCPA, CPRA or other laws may result in liability through private actions (subject to statutorily defined damages in the event of certain data breaches) and enforcement. The GDPR, CCPA, CPRA and 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 if the products, intellectual property and technologies that are acquired or licensed are not successful. 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 collaboration with 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 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 and tax return audits and reviews in the United States and various foreign jurisdictions, including Germany and Ireland. 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. For example, the current U.S. Presidential administration has proposed to increase the U.S. corporate income tax rate from its current 21%, implement a minimum tax on book income and increase taxation of international business operations, among numerous other corporate tax reform proposals. 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.

In addition, significant judgment is required in determining our worldwide provision for income taxes. Various factors may have favorable or unfavorable effects on our income tax rate including, but not limited to, our portion of the non-deductible annual branded prescription drug fee, the accounting for stock options and other share-based awards, mergers/acquisitions and restructurings, ability to maintain manufacturing and other operational activities in our Irish facilities, changes in the mix of earnings in the various tax jurisdictions in which we operate, changes in overall levels of pre-tax earnings, resolution of federal, state and foreign income tax audits. The impact on our income tax provision resulting from the above mentioned factors may be significant.

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, 2021:

	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, 2021	750		$ 68.57	716		$ 6,414
August 1 - August 31, 2021	1,212		$ 70.19	727		$ 6,363
September 1 - September 30, 2021	653		$ 71.29	623		$ 6,318
Total	2,615	[2]	$ 70.00	2,066	[2]	

[1] In the first quarter of 2016, our Board of Directors authorized a $12.0 billion share repurchase program (“2016 Program”). 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, 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)	2.1	Agreement and Plan of Merger, dated September 13, 2020, among Immunomedics, Inc., Gilead Sciences, Inc. and Maui Merger Sub, Inc.
(2)	3.1	Restated Certificate of Incorporation of Registrant
(2)	3.2	Amended and Restated Bylaws of Registrant
	4.1	Reference is made to Exhibit 3.1 and Exhibit 3.2
(3)	4.2	Indenture related to Senior Notes, dated as of March 30, 2011, between Registrant and Wells Fargo, National Association, as Trustee
(3)	4.3	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)
(4)	4.4	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)
(5)	4.5	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)
(6)	4.6	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)
(7)	4.7	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)
(8)	4.8	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)
(9)	4.9	Eighth Supplemental Indenture, dated as of September 30, 2020, between the Company and Wells Fargo Bank, National Association, as Trustee (including form of notes)
(10)	4.10	Description of Registrant's Securities
(11)	10.1*	Gilead Sciences, Inc. 2004 Equity Incentive Plan, amended and restated May 10, 2017
(12)	10.2*	Amendment No. 1 to Gilead Sciences, Inc. 2004 Equity Incentive Plan, amended and restated May 10, 2017
(13)	10.3*	Form of employee stock option agreement under 2004 Equity Incentive Plan (for grants made in 2011 through 2018)
(14)	10.4*	Form of employee stock option agreement under 2004 Equity Incentive Plan (for grants made in 2019)
(15)	10.5*	Form of global employee stock option agreement under 2004 Equity Incentive Plan (4 year vest) (for grants made in 2019)
(16)	10.6*	Form of global employee stock option agreement under 2004 Equity Incentive Plan (4 year vest) (for grants made in 2020)
(17)	10.7*	Form of global employee stock option agreement under 2004 Equity Incentive Plan (4 year vest) (for grants commencing in 2021)
(18)	10.8*	Form of non-employee director stock option agreement under 2004 Equity Incentive Plan (for grants made in 2009 through 2012)
(19)	10.9*	Form of non-employee director stock option agreement (U.S.) under 2004 Equity Incentive Plan (for grants made in 2013)
(19)	10.10*	Form of non-employee director stock option agreement (non-U.S.) under 2004 Equity Incentive Plan (for grants made in 2013)
(20)	10.11*	Form of non-employee director stock option agreement under 2004 Equity Incentive Plan (for grants made in 2014 through 2018)
(14)	10.12*	Form of non-employee director stock option agreement under 2004 Equity Incentive Plan (for grants made in 2019)
(21)	10.13*	Form of non-employee director stock option agreement under 2004 Equity Incentive Plan (for grants made in 2020)
(14)	10.14*	Form of performance share award agreement - TSR Goals (U.S.) under 2004 Equity Incentive Plan (for grants made in 2019)
(16)	10.15*	Form of performance share award agreement - TSR Goals (U.S.) under 2004 Equity Incentive Plan (for grants made in 2020)
(17)	10.16*	Form of performance share award agreement - TSR Goals (U.S.) under 2004 Equity Incentive Plan (for grants commencing in 2021)
(14)	10.17*	Form of performance share award agreement - Revenue Goals (U.S.) under 2004 Equity Incentive Plan (for grants made in 2019)
(16)	10.18*	Form of performance share award agreement - Revenue Goals (U.S.) under 2004 Equity Incentive Plan (for grants made in 2020)
(17)	10.19*	Form of performance share award agreement - Revenue Goals (U.S.) under 2004 Equity Incentive Plan (for grants commencing in 2021)
(13)	10.20*	Form of employee restricted stock unit issuance agreement under 2004 Equity Incentive Plan (for grants made in 2011 through 2018)
(14)	10.21*	Form of employee restricted stock unit issuance agreement under 2004 Equity Incentive Plan (for grants made in 2019)
(15)	10.22*	Form of global employee restricted stock unit issuance agreement under 2004 Equity Incentive Plan (4 year vest) (for grants made in 2019)
(16)	10.23*	Form of global employee restricted stock unit issuance agreement under 2004 Equity Incentive Plan (4 year vest) (for grants made in 2020)

(17)	10.24*	Form of global employee restricted stock unit issuance agreement under 2004 Equity Incentive Plan (4 year vest) (for grants commencing in 2021)
(21)	10.25*	Form of non-employee director restricted stock unit issuance agreement under 2004 Equity Incentive Plan (for grants made in 2020)
(21)	10.26*	Gilead Sciences, Inc. 2018 Equity Incentive Plan, amended and restated April 7, 2020
(22)	10.27*	Gilead Sciences, Inc. Employee Stock Purchase Plan, amended and restated January 22, 2015
(14)	10.28*	Gilead Sciences, Inc. 2005 Deferred Compensation Plan, amended and restated April 19, 2016
(21)	10.29*	Gilead Sciences, Inc. Severance Plan, amended and restated May 5, 2020
(16)	10.30*	Gilead Sciences, Inc. Corporate Annual Incentive Plan, amended and restated January 1, 2020
(24)	10.31*	Offer Letter between Registrant and Daniel O'Day, dated November 30, 2018
(14)	10.32*	Stock option agreement for Daniel O'Day under 2004 Equity Incentive Plan
(14)	10.33*	Performance share award agreement for Daniel O'Day (for TSR Goals in 2019) under 2004 Equity Incentive Plan
(14)	10.34*	Performance share award agreement for Daniel O'Day (for Revenue Goals in 2019) under 2004 Equity Incentive Plan
(14)	10.35*	Form of restricted stock unit issuance agreement for Daniel O'Day (in 2019) under 2004 Equity Incentive Plan
(14)	10.36*	Offer Letter between Registrant and Johanna Mercier, dated May 21, 2019
(21)	10.37*	Letter Agreement between Registrant and Johanna Mercier, dated May 4, 2020
(16)	10.38*	Global stock option agreement for Johanna Mercier (in 2019) under 2004 Equity Incentive Plan
(16)	10.39*	Restricted stock unit issuance agreement for Johanna Mercier (for Performance Objectives in 2019-2020) under 2004 Equity Incentive Plan
(16)	10.40*	Global restricted stock unit issuance agreement for Johanna Mercier (in 2019) under 2004 Equity Incentive Plan
(16)	10.41*	Offer Letter between Registrant and Merdad Parsey, dated September 29, 2019
(16)	10.42*	Global stock option agreement for Merdad Parsey (in 2019) under 2004 Equity Incentive Plan
(16)	10.43*	Global restricted stock unit issuance agreement for Merdad Parsey (in 2019) under 2004 Equity Incentive Plan
(25)	10.44*	Form of Indemnity Agreement entered into between Registrant and its directors and executive officers
(25)	10.45*	Form of Employee Proprietary Information and Invention Agreement entered into between Registrant and certain of its officers and key employees
(26)	10.46*	Form of Employee Proprietary Information and Invention Agreement entered into between Registrant and certain of its officers and key employees (revised September 2006)
+(27)	10.47	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)
+(28)	10.48	Amendment Agreement between Registrant and IOCB/REGA, dated December 27, 2000, amending the 1991 License Agreement and the December 1992 License Agreement
+(29)	10.49	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
+(30)	10.50	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
+(31)	10.51	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
+(32)	10.52	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
+(32)	10.53	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
++(33)	10.54	Amended and Restated EVG License Agreement by and between Japan Tobacco Inc. and Registrant, dated November 29, 2018
++(33)	10.55	Master Agreement by and between Registrant, Gilead Sciences K.K. and Japan Tobacco Inc., dated November 29, 2018
+(34)	10.56	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
+(35)	10.57	License Agreement by and among Kite Pharma, Inc., Cabaret Biotech Ltd. and Dr. Zelig Eshhar, dated December 12, 2013
++(15)	10.58	Option, License and Collaboration Agreement by and between Galapagos NV and Registrant, dated July 14, 2019
	31.1**	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

31.2**	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
32***	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)
101.INS**	XBRL Instance Document - The instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH**	Inline XBRL Taxonomy Extension Schema Document
101.CAL**	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF**	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB**	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE**	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File, formatted in Inline XBRL (included as Exhibit 101)

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

* Management contract or compensatory plan or arrangement.
** Filed herewith.
*** Furnished herewith.
\+ Certain confidential portions of this Exhibit were omitted by means of marking such portions with an asterisk (the Mark). This Exhibit has been filed separately with the Secretary of the Securities and Exchange Commission without the Mark pursuant to Registrant's Application Requesting Confidential Treatment under Rule 24b-2 under the Securities Exchange Act of 1934, as amended.
++ Certain confidential portions of this Exhibit were omitted by means of marking such portions with the Mark because the identified confidential portions are (i) not material and (ii) would be competitively harmful if publicly disclosed.

SIGNATURES

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

GILEAD SCIENCES, INC.
(Registrant)

Date: November 3, 2021

/s/ DANIEL P. O'DAY

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

Date: November 3, 2021

/s/ ANDREW D. DICKINSON

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

Exhibit 31.1

CERTIFICATION

I, Daniel P. O'Day, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Gilead Sciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 3, 2021

/s/ DANIEL P. O'DAY

Daniel P. O'Day
Chairman and Chief Executive Officer

Exhibit 31.2

CERTIFICATION

I, Andrew D. Dickinson, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Gilead Sciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 3, 2021

/s/ ANDREW D. DICKINSON

Andrew D. Dickinson
Chief Financial Officer

Exhibit 32

CERTIFICATIONS

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. § 1350, as adopted), Daniel P. O'Day, the Chairman and Chief Executive Officer of Gilead Sciences, Inc. (the Company), and Andrew D. Dickinson, the Chief Financial Officer of the Company, each hereby certifies that, to the best of his or her knowledge:

1. The Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2021 (the Report) fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 3, 2021

/s/ DANIEL P. O'DAY
Daniel P. O'Day
Chairman and Chief Executive Officer

/s/ ANDREW D. DICKINSON
Andrew D. Dickinson
Chief Financial Officer

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the SEC and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.