because

every day counts

2024 annual report

EXELIXIS

Key Corporate Highlights

1 cohesive Exelixis team united in our mission to help cancer patients recover stronger and live longer

$1.8B in cabozantinib franchise U.S. net product revenues in fiscal year 2024, an increase of 11% from 2023

3 internal clinical programs with best- and/or first-in-class potential in phase 1 development, with the potential for additional Investigational New Drug filings in 2025

6 ongoing/planned pivotal studies of zanzalintinib, a third-generation oral tyrosine kinase inhibitor, which we believe has the potential to surpass cabozantinib both in scope and scale

$1.2B returned to shareholders through stock repurchase programs from March 2023 to the end of fiscal year 2024, including $655.6 million returned in 2024 alone

To Our Stockholders

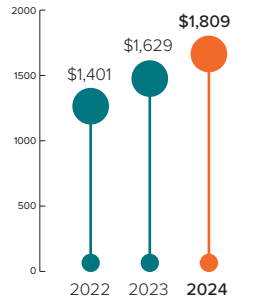
The clinical and commercial success of CABOMETYX® (cabozantinib) — the number one biotech oncology launch since 2016 — has demonstrated Exelixis can deliver on improving the standards of care for patients with cancer and creating long-term value for our stakeholders.

Throughout 2024, with cabozantinib as our foundation, we made important progress toward our goal of establishing Exelixis as a multi-product, multi-franchise oncology company with a leadership position in genitourinary (GU) and gastrointestinal (GI) cancers. We grew the commercial CABOMETYX business, obtained clarity on the cabozantinib patent estate to enable U.S. franchise revenues through 2030, expanded our clinical development program for zanzalintinib through a new collaboration with Merck, and made key preparations for an early 2025 U.S. regulatory approval for two new indications for CABOMETYX in neuroendocrine tumors (NET). We expect to continue this strong momentum into 2025 as we bring CABOMETYX to patients in this important new disease area, deliver data from and initiate new pivotal trials for zanzalintinib, and expand our pipeline, all in service of the Exelixis mission.

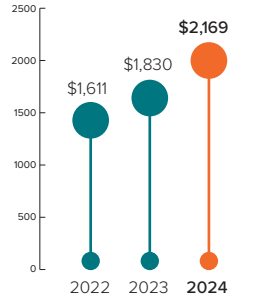
Cabozantinib: Our Growing Franchise

Since its first approval in 2012, cabozantinib has grown from an orphan product into a successful global oncology franchise. In 2024, cabozantinib generated over $2.5 billion in global net product revenues from Exelixis and its partners, including $1.8 billion in the U.S. During the year, the tablet form of cabozantinib, CABOMETYX, maintained its status as the leading tyrosine kinase inhibitor (TKI) for renal cell carcinoma (RCC), the most common form of kidney cancer in adults, and provided significant benefit for patients in its other labeled indications for forms of liver and thyroid cancer.

Cabozantinib's strong 2024 performance across all its key commercial metrics, in conjunction with recent corporate and product development milestones, drives our optimism for the franchise's revenue outlook through 2030. We expect continued growth of our base business, where CABOMETYX in combination with nivolumab is the most prescribed TKI+immunotherapy regimen in first-line RCC and the market leader for second-line RCC as a monotherapy. In support of future growth, we are excited about the U.S. FDA's approval of CABOMETYX in March 2025 for certain types of previously treated advanced NET. Drawing on our commercial experience in RCC, we aim to establish CABOMETYX as the small molecule market leader in NET, a group of tumor types that lack therapeutic options that broadly address this wide-ranging heterogeneous disease in patients who have progressed on prior therapy. With so much potential in RCC, NET and our other commercial indications, we believe U.S. net product revenues for the cabozantinib franchise could reach $3 billion in 2030.



Cabozantinib Franchise
U.S. Net Product Revenues
(in millions)



U.S. Total Revenues
(in millions)

Revenues from the cabozantinib franchise fuel the development of our pipeline and with it, our potential for further long-term value creation. Zanzalintinib, our most advanced investigational compound, is a third-generation oral TKI with clinical and commercial opportunities that we believe can surpass the cabozantinib franchise both in scope and scale, representing a key component of Exelixis' mid- and long-term revenue growth.

Zanzalintinib: Multiple Data Readouts in 2025

Zanzalintinib will take center stage in 2025 as we anticipate delivering data from multiple pivotal trials and launching new studies with our partner, Merck. We are intentionally focusing clinical development in settings where we can evaluate zanzalintinib against a contemporary standard of care, while expanding into new therapeutic areas where cabozantinib is not commercially available. In the second half of the year, dependent on event rates, we're anticipating top-line results from STELLAR-303, which is evaluating zanzalintinib in combination with Roche's atezolizumab in advanced colorectal cancer, and STELLAR-304, which is evaluating zanzalintinib in combination with Bristol Myers Squibb's nivolumab in advanced non-clear cell RCC, a set of different histological subtypes where patient outcomes are generally worse than in clear cell RCC. Also in the second half of 2025, we will make a decision on whether to advance to the phase 3 portion of STELLAR-305, our pivotal study of zanzalintinib in combination with Merck's pembrolizumab in a form of head and neck cancer, based on an analysis from the phase 2 portion of the trial.

New zanzalintinib pivotal studies planned for 2025 include STELLAR-311, which will evaluate zanzalintinib against an active comparator, everolimus, in patients with advanced NET who have received up to one prior systemic treatment – building on CABOMETYX's anticipated success in this setting and potentially supporting a regulatory filing for zanzalintinib in earlier lines of therapy. And as announced in October 2024, we are collaborating on a series of trials evaluating zanzalintinib with two important Merck therapies: pembrolizumab in the ongoing STELLAR-305 trial, and belzutifan in a phase 1/2 study and two phase 3 pivotal trials in RCC. Altogether, we expect to have six zanzalintinib pivotal trials ongoing by the end of 2025, which could tee up at least one commercial launch per year starting as early as 2026. We project that as we launch in successive commercial indications, U.S. net product revenues for zanzalintinib could reach $5 billion by 2033, the majority coming from a roughly equal split in GU and GI cancer indications, with an important contribution from the head and neck cancer treatment opportunity as well.

The Pipeline: Clinical Promise, Franchise Possibility

We're applying learnings from our experience with cabozantinib and zanzalintinib as we optimize our earlier-stage pipeline of differentiated cancer therapies with first- and/or best-in-class potential. Our focus is on rapidly and efficiently profiling compounds and prioritizing those with the highest chance of clinical and commercial success. You can see a snapshot of the current pipeline on page 4 of this report. In 2025, we are advancing the phase 1 development of XL309, our small molecule inhibitor of USP1, while accelerating enrollment of the first-in-human study for XB010, our antibody-drug conjugate targeting the tumor antigen 5T4 and carrying

the cytotoxic payload MMAE, as we work toward generating data to potentially support moving these programs into full development. And earlier this year, the U.S. FDA cleared our Investigational New Drug (IND) application for XB628, a first-in-class bispecific antibody that simultaneously targets PD-L1 and NKG2A. We anticipate presenting preclinical data from several of our pipeline programs and filing additional IND applications over the course of this year.

Allocating Capital in Service to Our Stakeholders

As we advance our development portfolio, we're simultaneously committed to a balanced capital allocation approach that allows us to reinvest in the business and evaluate appropriate business development (BD) opportunities while returning excess capital to shareholders. We've paired prudent expense management with an approximately $1 billion annual investment in R&D to efficiently accomplish the discovery and development objectives necessary for our mission. At the same time, we're able to execute on our BD objectives in pursuit of late-stage clinical assets in the GU and GI oncology spaces where we can leverage our experience and expertise to drive clinical and commercial success.

Ongoing reinvestment in the business happens alongside our stock repurchase program (SRP), which returned over $1.2 billion in capital to shareholders between March 2023 and the end of 2024. In February 2025, we announced plans to complete the existing SRP and launch an additional program – the fourth since 2023 – that enables us to repurchase $500 million more of our stock by the end of this year.

An Ambitious Plan to Help More Patients Recover Stronger and Live Longer

Resilience is an Exelixis hallmark, and throughout our over 30-year history we've never shied away from addressing a clinical or business challenge head-on. As we build on our current global franchise and aspire to become a multi-product, multi-franchise oncology company, we're drawing on our leadership expertise in GU oncology while pursuing a similar leadership position in the GI space both for cabozantinib and zanzalintinib. Our approach is rooted in running rigorously designed, well-executed pivotal studies that ask the right clinical questions and challenge the current standards of care. In this way, our success as a business is intrinsically tied to our ability to do more for the patients we serve, as it should.

As we move through 2025, we're excited for the anticipated data readouts, pivotal trial initiations, and other milestones that will define the upcoming opportunities for cabozantinib, zanzalintinib, and our earlier-stage programs – and for the next phase of Exelixis' continued evolution. We're also looking forward to our next R&D Day, which will take place later this year, during which we'll review our clinical and pipeline progress and highlight several emerging areas of research. On behalf of our driven and dedicated team of employees across the country, thank you for your continued interest in and support of Exelixis as we innovate medicines that can change lives and give patients more hope for the future.

Michael M. Morrissey, Ph.D.
President and Chief Executive Officer
Exelixis, Inc.

A Diversified Oncology Pipeline of Small Molecules and Biotherapeutics

In addition to the six ongoing/planned zanzalintinib pivotal trials, we are advancing internal phase 1 programs with best- and/or first-in-class potential. Our preclinical programs also include innovative biotherapeutics that could be the subject of additional future IND filings, pending continued supportive data.

Pre-IND	Phase 1	Phase 1b/2	Pivotal
XB371: TF-TOPOi	**XL309:** USP1	**Zanzalintinib:** MET/VEGFR/AXL *Multiple solid tumors*	**Zanzalintinib:** STELLAR-303 *3L+ CRC*
XB064: ILT2	**XB010:** 5T4-MMAE		**Zanzalintinib:** STELLAR-304 *nccRCC*
XB033: IL13Rα2-TOPOi	**XB628:** PD-L1 + NKG2A	**Zanzalintinib:** *RCC*	**Zanzalintinib:** STELLAR-305 *HNSCC*
XB773: DLL3-TOPOi	**ADU-1805:** SIRPα		**Zanzalintinib:** STELLAR-311 *NET*
			Zanzalintinib: *RCC*
			Zanzalintinib: *RCC*

Drug Modality

- Small Molecule
- Monoclonal Antibody
- Bispecific Antibody
- Antibody-Drug Conjugate

Combination Partner

- PD-(L)1
- Novel ICI (e.g., LAG-3)
- Other (e.g., HIF2α)

3L+ = third-line and later
CRC = colorectal carcinoma
DLL3 = delta-like ligand 3
HIF2α = hypoxia-inducible factor 2 alpha
HNSCC = head and neck squamous cell carcinoma
ICI = immune checkpoint inhibitor
IL13Rα2 = interleukin 13 receptor alpha 2
ILT2 = Ig-like transcript 2
LAG-3 = lymphocyte-activation gene 3
MMAE = monomethyl auristatin E
nccRCC = non-clear cell renal cell carcinoma
NET = neuroendocrine tumors
NKG2A = natural killer cell receptor group 2A
PD-L1 = programmed death-ligand 1
PD-(L)1 = PD-L1 or programmed cell death protein 1 (PD-1)
RCC = renal cell carcinoma
SIRPα = signal-regulatory protein alpha
TF = tissue factor
TOPOi = topoisomerase inhibitor
USP1 = ubiquitin specific peptidase 1
VEGFR = vascular endothelial growth factor receptor

Six Ongoing or Planned Zanzalintinib Pivotal Studies in 2025

Pivotal Study Setting	Gastrointestinal Cancers		Genitourinary Cancers		Head & Neck Cancer
	STELLAR-303	STELLAR-311	STELLAR-304	Merck RCC Studies	STELLAR-305
	3L+, non-MSI high, non-dMMR mCRC	Advanced NET (pNET & epNET)	1L, nccRCC: papillary, unclassified, and translocation-associated	Zanzalintinib + Belzutifan Phase 3 in RCC	PD-L1+ 1L metastatic HNSCC
				Study #1 *Details TBA*	
				Zanzalintinib + Belzutifan Phase 3 in RCC	
				Study #2 *Details TBA*	
Arms	1:1 Zanza + Atezo vs Regorafenib	1:1 Zanzalintinib vs Everolimus	2:1 Zanza + Nivo vs Sunitinib		1:1 Zanza + Pembro vs Pembrolizumab

1L = first-line
3L+ = third-line and later
mCRC = metastatic colorectal cancer
NET = neuroendocrine tumors
pNET = pancreatic NET
epNET = extra-pancreatic NET
RCC = renal cell carcinoma
nccRCC = non-clear cell RCC
HNSCC = head and neck squamous cell carcinoma
PD-L1+ = programmed death-ligand 1 positive
MSI = microsatellite instability
dMMR = mismatch repair deficient
Zanza = zanzalintinib
Atezo = atezolizumab
Nivo = nivolumab
Pembro = pembrolizumab
TBA = to be announced

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

FORM 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended January 3, 2025
or
☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to

Commission File Number: 000-30235

EXELIXIS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**04-3257395**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

1851 Harbor Bay Parkway
Alameda, CA 94502
(650) 837-7000

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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 $0.001 Par Value per Share	**EXEL**	**The Nasdaq Stock Market LLC**

Securities registered pursuant to Section 12(g) of the Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter: approximately $4.8 billion. Excludes shares of the registrant's common stock held by persons who were directors and/or executive officers of the registrant at June 28, 2024 on the basis that such persons may be deemed to have been affiliates of the registrant at such date. Exclusion of such shares should not be construed to indicate that any such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the registrant or that such person is controlled by or under common control with the registrant.

Number shares of the registrant's common stock outstanding as of February 3, 2025: 279,881,450

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A, not later than May 3, 2025, in connection with the registrant's 2025 Annual Meeting of Stockholders are incorporated herein by reference into Part III of this Annual Report on Form 10-K.

EXELIXIS, INC.
ANNUAL REPORT ON FORM 10-K
INDEX

SPECIAL NOTE REGARDING FORWARD LOOKING STATEMENTS

Some of the statements under the captions "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business" and elsewhere in this Annual Report on Form 10-K are forward-looking statements. These statements are based on our current expectations, assumptions, estimates and projections about our business and our industry and involve known and unknown risks, uncertainties and other factors that may cause our company's or our industry's results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied in, or contemplated by, the forward-looking statements. Our actual results and the timing of events may differ significantly from the results discussed in the forward-looking statements. Factors that might cause such a difference include those discussed under the heading "Item 1A. Risk Factors" as well as those discussed elsewhere in this Annual Report on Form 10-K.

These and many other factors could affect our future financial and operating results. We undertake no obligation to update any forward-looking statement to reflect events after the date of this report.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

RISK FACTOR SUMMARY

Investing in our securities involves a high degree of risk. Below is a summary of material factors that make an investment in our securities speculative or risky. Importantly, this summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, as well as other risks that we face, can be found under the heading "Item 1A. Risk Factors" below.

- *Our ability to grow our company is dependent upon the commercial success of CABOMETYX in its approved indications and the continued clinical development, regulatory approval, clinical acceptance and commercial success of the cabozantinib franchise in additional indications.*
- *If we are unable to obtain or maintain coverage and reimbursement for our products from government and other third-party payers, our business will suffer.*
- *Pricing for pharmaceutical products, both in the U.S. and in foreign countries, has come under increasing attention and scrutiny by federal, state and foreign national governments, legislative bodies and enforcement agencies. Initiatives arising from this scrutiny may result in changes that have the effect of reducing our revenue or harming our business or reputation.*
- *The timing of the entrance of generic competitors to CABOMETYX and legislative and regulatory action designed to reduce barriers to the development, approval and adoption of generic drugs in the U.S. could limit the revenue we derive from our products, most notably CABOMETYX, which could have a material adverse impact on our business, financial condition and results of operations.*
- *We may be unable to expand our discovery and development pipeline, which could limit our growth and revenue potential.*
- *Clinical testing of cabozantinib for new indications, or of our other new product candidates, such as zanzalintinib, is a lengthy, costly, complex and uncertain process that may ultimately fail to demonstrate sufficiently differentiated safety and efficacy data for those products to compete in our highly competitive market environment.*
- *The regulatory approval processes of the U.S. Food and Drug Administration and comparable foreign regulatory authorities are lengthy, uncertain and subject to change, and may not result in regulatory approvals for additional cabozantinib indications or for our other product candidates, such as zanzalintinib, which could have a material adverse impact on our business, financial condition and results of operations.*
- *Our profitability could be negatively impacted if expenses associated with our extensive drug discovery, clinical development, business development and commercialization activities grow more quickly than the revenues we generate.*
- *Our clinical, regulatory and commercial collaborations with major companies make us reliant on those companies for their continued performance and investments, which subjects us to a number of risks. For example, we rely on*

Ipsen Pharma SAS (Ipsen) and Takeda Pharmaceutical Company Limited (Takeda) for the commercial success of CABOMETYX in its approved indications outside of the U.S., and we are unable to control the amount or timing of resources expended by these collaboration partners in the commercialization of CABOMETYX in its approved indications outside of the U.S. In addition, our growth potential is dependent in part upon companies with which we have entered research collaborations, in-licensing arrangements and similar business development relationships.

- *We are subject to healthcare laws, regulations and enforcement, as well as laws and regulations relating to privacy, data collection and processing of personal data; our failure to comply with those and other laws could have a material adverse impact on our business, financial condition and results of operations.*
- *Data breaches and other cybersecurity incidents impacting our information technology operations and infrastructure could compromise our intellectual property or other sensitive information, damage our operations and cause significant harm to our business and reputation.*
- *If we are unable to adequately protect our intellectual property, third parties may be able to use our technology, which could adversely affect our ability to compete in the market.*
- *The loss of key personnel or the inability to retain and, where necessary, attract additional personnel could impair our ability to operate successfully.*
- *Our goals and disclosures related to environmental, social and governance matters subjects us to risks, including risks to our market perception and stock price.*

BASIS OF PRESENTATION

We have adopted a 52- or 53-week fiscal year policy that generally ends on the Friday closest to December 31st. Fiscal year 2024, which was a 53-week fiscal year, ended on January 3, 2025; fiscal year 2023, which was a 52-week fiscal year, ended on December 29, 2023; and fiscal year 2022, which was a 52-week fiscal year, ended on December 30, 2022. For convenience, references in this report as of and for the fiscal years ended January 3, 2025, December 29, 2023 and December 30, 2022, are indicated as being as of and for the years ended December 31, 2024, 2023 and 2022, respectively. In fiscal year 2025, the annual period will end on January 2, 2026 and will be a 52-week fiscal year.

PART I

Item 1. Business.

Overview

Exelixis, Inc. (Exelixis, we, our or us) is an oncology company innovating next-generation medicines and combination regimens at the forefront of cancer care. We have produced four marketed pharmaceutical products, two of which are formulations of our flagship molecule, cabozantinib, and we are steadily advancing and evolving our product pipeline portfolio, including our lead investigational asset, zanzalintinib, currently the focus of an extensive late-stage clinical development program. With a rational and disciplined approach to investment, we are leveraging our internal experience and expertise, and the strength of strategic partnerships, to identify and pursue opportunities across the landscape of scientific modalities, including small molecules, biotherapeutics and antibody-drug conjugates (ADCs).

Sales related to cabozantinib account for the majority of our revenues. Cabozantinib is an inhibitor of multiple tyrosine kinases, including MET, AXL, VEGF receptors and RET and has been approved by the U.S. Food and Drug Administration (FDA) and in 67 other countries: as CABOMETYX® (cabozantinib) tablets for advanced renal cell carcinoma (RCC) (both alone and in combination with Bristol-Myers Squibb Company's (BMS) nivolumab (OPDIVO®)), for previously treated hepatocellular carcinoma (HCC) and for previously treated, radioactive iodine (RAI)-refractory differentiated thyroid cancer (DTC); and as COMETRIQ® (cabozantinib) capsules for progressive, metastatic medullary thyroid cancer (MTC). For physicians treating these types of cancer, cabozantinib has become or is becoming an important medicine in their selection of effective therapies.

The other two products resulting from our discovery efforts are: COTELLIC® (cobimetinib), an inhibitor of MEK approved as part of multiple combination regimens to treat specific forms of advanced melanoma and marketed under a collaboration with Genentech, Inc. (a member of the Roche Group) (Genentech); and MINNEBRO® (esaxerenone), an oral, non-steroidal, selective blocker of the mineralocorticoid receptor (MR), approved for the treatment of hypertension in Japan and licensed to Daiichi Sankyo Company, Limited (Daiichi Sankyo). See "—Collaborations and Business Development Activities—Other Collaborations."

2024 was our eighth consecutive year of annual profitability; it featured growth in net product revenues of approximately 11% year-over-year as a result of increased sales of our cabozantinib products in the U.S., supplemented by an approximately 12% year-over-year increase in royalties earned pursuant to collaboration agreements with our ex-U.S. partners. We plan to continue leveraging our operating cash flows to advance a broad array of diverse biotherapeutics and small molecule programs for the treatment of cancer, as well as to support ongoing company-sponsored and externally sponsored trials evaluating cabozantinib. Furthest along in our pipeline is zanzalintinib, a novel, potent, third-generation oral tyrosine kinase inhibitor (TKI) that targets VEGF receptors, MET and the TAM kinases (TYRO3, AXL and MER). Our zanzalintinib program includes a series of ongoing and planned pivotal trials to explore its therapeutic potential in colorectal cancer (CRC), RCC, non-clear cell (ncc)RCC, squamous cell cancers of the head and neck (SCCHN) and neuroendocrine tumors (NET), as well as earlier-stage trials. Our other pipeline programs in phase 1 development each have best-in-class potential and include: XL309, a small molecule inhibitor of USP1, which has emerged as a synthetic lethal target in the context of BRCA-mutated tumors; XB010, an ADC consisting of a monomethyl auristatin E (MMAE) payload conjugated to a monoclonal antibody (mAb) targeting the tumor antigen 5T4; and XL495, a small molecule inhibitor of PKMYT1. We complement our internal drug discovery and development efforts by in-licensing investigational oncology assets or obtaining options to acquire other investigational oncology assets from third parties if they demonstrate evidence of clinical success. Examples of this approach include XL309 and ADU-1805, a clinical-stage and potentially best-in-class mAb that targets SIRPα.

Exelixis Marketed Products: CABOMETYX and COMETRIQ

As detailed below, CABOMETYX and COMETRIQ have been approved to treat patients with various forms of cancer by the FDA for the U.S. market, the European Medicines Agency (EMA) for the European Union (EU) market and the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) for the Japanese market, as well as by comparable regulatory authorities across other markets worldwide.

Product	Indication	Approval Date	Regimen	Major Markets
CABOMETYX® (cabozantinib)	**Renal Cell Carcinoma (RCC)**			
	Patients with advanced RCC who have received prior anti-angiogenic therapy	April 25, 2016	Monotherapy	U.S.
	Advanced RCC in adults following prior VEGF-targeted therapy	September 9, 2016	Monotherapy	EU
	Patients with advanced RCC	December 19, 2017	Monotherapy	U.S.
	First-line treatment of adults with intermediate- or poor-risk advanced RCC	May 17, 2018	Monotherapy	EU
	Patients with curatively unresectable or metastatic RCC	March 25, 2020	Monotherapy	Japan
	First-line treatment of patients with advanced RCC	January 22, 2021	Combination with nivolumab	U.S.
	First-line treatment for patients with advanced RCC	March 31, 2021	Combination with nivolumab	EU
	Patients with unresectable or metastatic RCC	August 25, 2021	Combination with nivolumab	Japan
	Hepatocellular Carcinoma (HCC)			
	HCC in adults who have previously been treated with sorafenib	November 15, 2018	Monotherapy	EU
	Patients with HCC who have been previously treated with sorafenib	January 14, 2019	Monotherapy	U.S.
	Patients with unresectable HCC that has progressed after cancer chemotherapy	November 27, 2020	Monotherapy	Japan
	Differentiated Thyroid Cancer (DTC)			
	Adult and pediatric patients 12 years of age and older with locally advanced or metastatic DTC that has progressed following prior VEGF receptor-targeted therapy and who are RAI-refractory or ineligible	September 17, 2021	Monotherapy	U.S.
	Adult patients with locally advanced or metastatic DTC, refractory pr not eligible to RAI who have progressed during or after prior systemic therapy	May 3, 2022	Monotherapy	EU
COMETRIQ® (cabozantinib)	**Medullary Thyroid Cancer (MTC)**			
	Patients with progressive, metastatic MTC	November 29, 2012	Monotherapy	U.S.
	Adult patients with progressive, unresectable locally advanced or metastatic MTC	March 25, 2014	Monotherapy	EU

In 2024, 2023 and 2022, we generated $1,809.4 million, $1,628.9 million and $1,401.2 million, respectively, in net product revenues from sales of CABOMETYX and COMETRIQ. Outside the U.S., we rely on collaboration partners for the commercialization of our cabozantinib products; Ipsen is responsible for all territories outside of the U.S. and Japan, and Takeda is responsible for the Japanese market. In 2024, 2023 and 2022, we earned $166.9 million, $148.5 million and $121.4 million, respectively, of royalties on net sales of cabozantinib products outside of the U.S. For additional information on the terms of our collaboration agreements with Ipsen and Takeda, see "—Collaborations and Business Development Activities—Cabozantinib Commercial Collaborations."

Renal Cell Carcinoma - CABOMETYX is a Leading TKI Treatment Option for Patients with Advanced RCC

CABOMETYX has become a standard of care for the treatment of patients with advanced RCC, and a growing number of these patients have been or will be treated with CABOMETYX. In 2024, approximately 33,200 patients with advanced kidney cancer required systemic therapy in the U.S., with over 21,000 patients receiving first-line treatment.

Since CABOMETYX was first approved, we have deployed our Medical Affairs and Commercial teams to educate physicians about CABOMETYX. We believe that the commercial success of CABOMETYX is attributable to the strength of the clinical data reflected in its FDA-approved labeling for advanced RCC. The indications for the treatment of advanced RCC in the CABOMETYX label are based on the results of the METEOR, CABOSUN and CheckMate -9ER clinical trials. In July 2015, we announced positive results of METEOR, a phase 3 pivotal trial comparing CABOMETYX to everolimus in patients with advanced RCC who have experienced disease progression following treatment with at least one prior VEGF receptor inhibitor. These results formed the basis for FDA approval in April 2016, following which CABOMETYX became the first single-agent therapy approved in the U.S. for previously treated advanced RCC to demonstrate statistically significant and clinically meaningful improvements in three key efficacy parameters in a global pivotal trial: overall survival (OS); progression-free survival (PFS); and objective response rate (ORR). To date, CABOMETYX remains the only single-agent therapy to have achieved these clinical results in previously treated advanced RCC. In October 2016, we announced positive results from CABOSUN, a randomized, open-label, active-controlled phase 2 trial conducted by the Alliance for Clinical Trials in Oncology (the Alliance), comparing cabozantinib with sunitinib in patients with previously untreated advanced RCC with intermediate- or poor-risk disease. These results formed the basis for FDA approval in December 2017 of CABOMETYX for previously untreated patients with advanced RCC. For this patient population, CABOMETYX is the only approved single-agent therapy to demonstrate improved PFS compared with sunitinib, a first-generation TKI that was the previous standard of care.

CABOMETYX has also demonstrated positive clinical results in combination with immune checkpoint inhibitors (ICIs), most notably in CheckMate -9ER, an open-label, randomized, multinational phase 3 pivotal trial evaluating CABOMETYX in combination with nivolumab versus sunitinib in patients with previously untreated, advanced or metastatic RCC. Results from CheckMate -9ER demonstrated that the combination of CABOMETYX and nivolumab doubled PFS and ORR and reduced the risk of disease progression or death by 40% compared with sunitinib and formed the basis for FDA approval of the combination in January 2021 as a first-line treatment of patients with advanced RCC. At five years of follow-up, the CheckMate -9ER results continued to show superior PFS and ORR in patients treated with CABOMETYX in combination with nivolumab over sunitinib, regardless of risk classification (as determined by International Metastatic Renal Cell Carcinoma Database Consortium scores). Superior OS was also observed in patients treated with the combination. These updated results will be featured in an oral presentation at the American Society of Clinical Oncology (ASCO) Genitourinary Cancers Symposium in February 2025 (ASCO GU 2025).

In addition, the National Comprehensive Cancer Network (NCCN), the nation's foremost non-profit alliance of leading cancer centers, has included the combination of CABOMETYX with nivolumab in its Clinical Practice Guidelines for Kidney Cancer as a Category 1 preferred option for the first-line treatment of patients with clear cell RCC across all risk groups, and as a Category 2A other recommended option for first-line nccRCC. The NCCN also lists single-agent CABOMETYX as a recommended regimen for patients with previously treated advanced clear cell RCC, supporting CABOMETYX's position in the RCC treatment landscape across lines of therapy.

In 2024, in markets outside the U.S., we continued to work closely with our collaboration partner Ipsen in support of its regulatory strategy and commercialization efforts for CABOMETYX, both as a single agent and in combination with nivolumab, as well as in preparation for submission of applications for potential additional approvals of CABOMETYX, and similarly with our collaboration partner Takeda with respect to the Japanese market. As a result of the approvals of CABOMETYX and/or the combination of CABOMETYX with nivolumab for RCC indications in 67 countries outside of the U.S., including the Member States of the EU, Japan, the U.K., Canada, Brazil, Taiwan, South Korea, Australia and Hong Kong,

CABOMETYX has continued to grow markedly outside the U.S. both in sales revenue and the number of RCC patients benefiting from its clinical effect.

Hepatocellular Carcinoma - CABOMETYX Offers an Important Alternative for Patients with Previously Treated HCC

Liver cancer is a leading cause of cancer death worldwide, accounting for more than 800,000 new cases and 700,000 deaths each year. In the U.S., the incidence of liver cancer has tripled over the past four decades. Although HCC is the most common form of liver cancer, making up about three-fourths of the more than 42,200 cases of liver cancer estimated to be diagnosed in the U.S. during 2025, this patient population has long been underserved. Prior to 2017, therapies for the treatment of HCC were limited in number. Biopharmaceutical companies have since developed new and demonstrably more effective therapies for previously untreated patients, including ICI combination therapies. These new treatment options have improved longer-term outcomes for HCC patients, thereby resulting in a greater number of them receiving multiple lines of therapy. Thus, the second- and later-line market for HCC therapies has become increasingly competitive, and we believe this trend may continue over the coming years, with monotherapy CABOMETYX maintaining an important place in the HCC treatment landscape.

The FDA approved the HCC indication for CABOMETYX in January 2019 was based on our phase 3 pivotal study, CELESTIAL. The CELESTIAL study met its primary endpoint, demonstrating that cabozantinib significantly improved OS compared to placebo. The NCCN has included CABOMETYX in its Clinical Practice Guidelines for Hepatocellular Carcinoma as a Category 1 option for the treatment of patients with HCC as a subsequent-line systemic therapy if disease progression occurs, providing further support for CABOMETYX as an important treatment option for eligible HCC patients.

Outside the U.S., the EMA's approval of CABOMETYX provided physicians in the EU with a second approved therapy for the second-line treatment of this aggressive and difficult-to-treat cancer, and approvals from Health Canada and the Japanese PMDA brought a much-needed treatment option to HCC patients in those countries. In addition to the Member States of the EU, Japan, the U.K. and Canada, CABOMETYX is also approved for previously treated HCC indications in Brazil, Taiwan, South Korea, Australia and Hong Kong, among other countries.

Differentiated Thyroid Cancer - An Opportunity for CABOMETYX to Help an Underserved Patient Population

Approximately 44,000 new cases of thyroid cancer will be diagnosed in the U.S. in 2025. Differentiated thyroid tumors, which make up about 90% of all thyroid cancers, are typically treated with surgery followed by ablation of the remaining thyroid with RAI. Approximately 5% to 15% of differentiated thyroid tumors are resistant to RAI treatment. With limited treatment options, these patients have a life expectancy of only three to six years from the time metastatic lesions are detected. In December 2020, we announced that COSMIC-311, our phase 3 pivotal trial evaluating cabozantinib in patients with RAI-refractory DTC who have progressed after receiving up to two prior VEGF receptor-targeted therapies, met one of its two primary endpoints, demonstrating a statistically significant improvement in PFS compared with placebo. In September 2021, the FDA approved CABOMETYX for the treatment of adult and pediatric patients 12 years of age and older with locally advanced or metastatic DTC that has progressed following prior VEGF receptor-targeted therapy and who are RAI-refractory or ineligible. Since our commercial launch of CABOMETYX in this patient group, we have established a strong market position for CABOMETYX amongst these previously treated DTC patients.

Outside the U.S., our collaboration partner Ipsen received approval from the EMA in May 2022 for CABOMETYX as a monotherapy for the treatment of adult patients with locally advanced or metastatic DTC, refractory or not eligible to RAI who have progressed during or after prior systemic therapy, which followed an approval from Health Canada in April 2022 to market CABOMETYX for a similar DTC indication.

Medullary Thyroid Cancer - COMETRIQ, the First Commercial Approval of Cabozantinib

Estimates suggest that there will be approximately 970 MTC cases diagnosed in the U.S. in 2025, and COMETRIQ has served as an important treatment option for these patients since January 2013. The FDA approved COMETRIQ for progressive, metastatic MTC based on our phase 3 trial, EXAM. The EXAM trial met its primary endpoint, demonstrating a statistically significant and clinically meaningful prolongation in PFS for cabozantinib compared with placebo. We are continuing to market COMETRIQ capsules for MTC patients at the labeled dose of 140 mg.

Exelixis Development Programs

Cabozantinib Development Program

Cabozantinib inhibits the activity of tyrosine kinases, including MET, AXL, VEGF receptors and RET. These receptor tyrosine kinases are involved in both normal cellular function and in pathologic processes such as oncogenesis, metastasis, tumor angiogenesis, drug resistance and maintenance of the tumor microenvironment. Beyond the established clinical benefits of cabozantinib in its approved indications, objective responses have been observed in patients treated with cabozantinib in additional individual tumor types investigated in early- and late-stage clinical trials, reflecting the medicine's broad clinical potential. We are continuing to evaluate cabozantinib in combination with ICIs in late-stage clinical trials that we sponsor, along with our collaboration partners. Independent investigators also conduct trials evaluating cabozantinib through our Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute's Cancer Therapy Evaluation Program (NCI-CTEP) or our investigator sponsored trial (IST) program. In addition to facilitating label expansion for the cabozantinib franchise, including our regulatory submissions for cabozantinib to treat NET based on the positive results from the phase 3 CABINET study, data sets from these externally sponsored clinical trials may also prove valuable by informing our development plans for zanzalintinib. Moreover, our collaboration partners Ipsen and Takeda have conducted trials in their respective territories through independently-sponsored programs, as well as co-funding select cabozantinib trials with us.

Combination Studies with BMS

In February 2017, we entered into a clinical collaboration agreement with BMS for the purpose of conducting clinical studies combining cabozantinib with BMS' PD-1 ICI, nivolumab, with or without BMS' CTLA-4 ICI, ipilimumab. Based on the data from CheckMate -9ER, the first clinical trial conducted under this collaboration, the FDA approved CABOMETYX in combination with nivolumab on January 22, 2021, as a first-line treatment of patients with advanced RCC. In May 2019, we initiated COSMIC-313, a multicenter, randomized, double-blinded, controlled phase 3 pivotal trial evaluating the triplet combination of cabozantinib, nivolumab and ipilimumab versus the combination of nivolumab and ipilimumab in patients with previously untreated advanced intermediate- or poor-risk RCC. Patients were randomized 1:1 to the experimental arm of the triplet combination or to the control arm of nivolumab and ipilimumab in combination with matched placebo. In August 2024, we announced the final analysis for the secondary endpoint of OS, which demonstrated that the experimental arm did not demonstrate an OS benefit over the control arm. Based on these results and the evolution of the first-line RCC treatment landscape since this study was initiated, we are not pursuing marketing authorization based on COSMIC-313. Data from the final analysis of OS in COSMIC-313 will be presented at the ASCO GU 2025. For additional information on the terms of the BMS clinical collaboration agreement, see "—Collaborations and Business Development Activities—Cabozantinib Development Collaborations—BMS Collaboration."

Combination Studies with Roche

We have also entered into collaborations with F. Hoffmann-La Roche Ltd. (Roche) for the purpose of evaluating the combination of cabozantinib and Roche's anti-PD-L1 ICI, atezolizumab, diversifying our exploration of cabozantinib combinations with ICIs.

COSMIC-021 - Locally Advanced or Metastatic Solid Tumors. In February 2017, we entered into a master clinical supply agreement with Roche. As part of the clinical supply agreement, in June 2017, we initiated COSMIC-021, a large phase 1b study evaluating the safety and tolerability of cabozantinib in combination with atezolizumab in patients with a wide variety of locally advanced or metastatic solid tumors. We are the trial sponsor of COSMIC-021, and Roche is providing atezolizumab free of charge. The study is divided into two parts: a dose-escalation phase, which was completed in 2018; and an expansion cohort phase, which completed enrollment in January 2022. Enrollment in the expansion phase of this study included 20 combination therapy tumor expansion cohorts in non-small cell lung cancer (NSCLC), mCRPC, RCC and various other tumor types.

CONTACT trials. Informed by the encouraging efficacy and safety data that emerged from COSMIC-021, we entered into a joint clinical research agreement with Roche in December 2019, pursuant to which the parties co-funded and undertook three pivotal phase 3 studies evaluating the combination of cabozantinib and atezolizumab. Two of these trials, CONTACT-01 in advanced NSCLC and CONTACT-03 in RCC (each sponsored by Roche) did not meet their respective primary endpoints. The third trial, CONTACT-02, is sponsored by us and evaluates the combination in patients with mCRPC as described below. For additional information on the terms of the Roche joint clinical research agreement, see "Collaborations and Business Development Activities – Cabozantinib Development Collaborations – Roche Collaboration."

CONTACT-02 - mCRPC. In June 2020, we and Roche initiated CONTACT-02, a global, multicenter, randomized, open-label phase 3 pivotal trial evaluating cabozantinib in combination with atezolizumab versus a second novel hormonal therapy (NHT) (either abiraterone and prednisone or enzalutamide) in patients with measurable extra-pelvic mCRPC who have progressed after treatment with one prior NHT. CONTACT-02 is informed by positive early-stage results from an mCRPC cohort of COSMIC-021, as well as by COMET-1, our earlier phase 3 trial that evaluated monotherapy cabozantinib in mCRPC. The CONTACT-02 trial enrolled 575 patients at 275 sites globally, and enrollment was completed in the second half of 2023. Patients were randomized 1:1 to the experimental arm of cabozantinib in combination with atezolizumab or to the control arm of a second NHT. The two primary efficacy endpoints for CONTACT-02 are BIRC-assessed PFS per Response Evaluation Criteria in Solid Tumors (RECIST) v. 1.1 and OS; key secondary and other efficacy endpoints include ORR, prostate-specific antigen response rate and duration of response (DOR). In August 2023, we announced positive top-line results that the trial met one of two primary endpoints, demonstrating a statistically significant improvement in PFS (HR: 0.65; 95% CI: 0.50-0.84; p=0.0007) in the predefined PFS intent-to-treat population (i.e., the first 400 randomized patients), and these data were presented at the American Society of Clinical Oncology Genitourinary Cancers Symposium in January 2024. For the second primary endpoint of OS, the final analysis for CONTACT-02, which was presented during the GU Tumours Proffered Paper Session: GU Tumours at the European Society for Medical Oncology Congress in September 2024 (ESMO 2024), showed a trend that favored the combination of cabozantinib and atezolizumab but was not statistically significant. Of note, the trend in OS benefit was consistently observed in key subgroups, including in patients with liver metastases— a subgroup of mCRPC patients with the poorest prognosis in need of new treatment options, and one we anticipate will grow in the coming years. The safety profile observed in the trial was reflective of the known safety profiles for each single agent and was consistent with the known tolerability profile of approved ICI-TKI combinations in advanced solid tumors. We continue to evaluate the timing of a potential regulatory submission to the FDA. Both Ipsen and Takeda opted into and are co-funding the trial.

According to the American Cancer Society, in 2025, approximately 313,000 new cases of prostate cancer will be diagnosed in the U.S., and over 35,000 people will die from the disease. Prostate cancer that has spread beyond the prostate and does not respond to androgen-suppression therapies—a common treatment for prostate cancer—is known as mCRPC. Men diagnosed with mCRPC often have a poor prognosis, which has an estimated survival of less than one to two years. We believe that cabozantinib in combination with atezolizumab, if ultimately approved by the FDA for an mCRPC indication, may be a compelling chemotherapy-free treatment option to respond to this significant unmet need.

Trials Conducted through our CRADA with NCI-CTEP and our IST Program

Clinical trials conducted with support from external partners have enabled further expansion of the cabozantinib development program with less burden on our internal development resources. In October 2011, we entered into a CRADA with NCI-CTEP for the clinical development of cabozantinib and have extended its term through October 2026. The CRADA reflects a commitment by NCI-CTEP to provide funding for the broad exploration of cabozantinib's potential in a wide variety of cancers, each representing a substantial unmet medical need. Investigational New Drug (IND) applications for trials under the CRADA are held by NCI-CTEP. NCI-CTEP also retains rights to any inventions made in whole or in part by NCI-CTEP investigators. However, for inventions that claim the use and/or the composition of cabozantinib, we have an automatic option to elect a worldwide, non-exclusive license to cabozantinib inventions for commercial purposes, with the right to sublicense to affiliates or collaborators working on our behalf, as well as an additional, separate option to negotiate an exclusive license to cabozantinib inventions. Further, before any trial proposed under the CRADA may commence, the protocol is subject to our review and approval. As reflected by the results from completed trials and ongoing clinical trials, we believe our CRADA with NCI-CTEP has facilitated and may continue to facilitate the expansion of the cabozantinib franchise in a cost-efficient manner. A summary of key trials under this collaboration is provided below.

CABINET - NET. The Alliance led the CABINET phase 3 pivotal study under the CRADA that evaluated cabozantinib versus placebo in patients who experienced progression after prior systemic therapy in two independently powered cohorts: one for advanced pancreatic NET (pNET) that enrolled 93 patients; and another for extra-pancreatic NET (epNET), historically referred to as carcinoid tumors) that enrolled 193 patients. Patients in both cohorts were randomized 2:1 to either the experimental arm of 60 mg cabozantinib daily or placebo, respectively. The primary endpoint for both studies was PFS per RECIST v. 1.1. In August 2023, enrollment into the study was stopped, patients were unblinded and those on placebo were offered treatment with cabozantinib due to dramatic improvements in PFS observed at interim analyses and based upon local investigator assessment. The data from CABINET demonstrated that cabozantinib substantially prolonged the time to disease progression or death in both pNET (HR: 0.27; 95% CI: 0.14-0.49; P<0.0001) and epNET (HR: 0.45; 95% CI: 0.30-0.66; P<0.0001) cohorts, and that the safety profile of cabozantinib observed in the trial was consistent with its known safety profile. In August 2024, we announced that the FDA had accepted our sNDA seeking approval for cabozantinib to

treat adult patients with previously treated, locally advanced/unresectable or metastatic, well- or moderately differentiated pNET or epNET, granted standard review in the U.S., and assigned a Prescription Drug User Fee Act (PDUFA) target action date of April 3, 2025. The FDA also granted orphan drug designation to cabozantinib for the treatment of pNET. Detailed final results from CABINET were presented during the NETs and Endocrine Tumours Proffered Paper Session at the ESMO 2024 and were concurrently published in *The New England Journal of Medicine* (NEJM). In November 2024, we announced that our sNDA would be discussed at an Oncologic Drugs Advisory Committee (ODAC) meeting in March 2025; however, in January 2025, we announced that the FDA had notified us that our sNDA would no longer be the subject of discussion at an ODAC. At the ASCO Gastrointestinal Cancers Symposium in January 2025 (ASCO GI 2025), the Alliance presented results in 116 patients in the epNET cohort with advanced gastrointestinal NET showing that cabozantinib was associated with an improvement in PFS compared with placebo in this subgroup of patients (PFS HR 0.50 (95%CI, 0.28-0.88)).

In 2024, the estimated prevalence of NET in the U.S. was more than 380,000 people and between 161,000 to 192,000 people are living with unresectable, locally advanced or metastatic NET. The number of people diagnosed with NET each year has been increasing. Most NET take years to develop and grow slowly, but eventually all patients with advanced or metastatic NET will develop refractory and progressing disease. NET can develop in any part of the body as epNET, but most commonly start in the gastrointestinal (GI) tract or in the lungs. The five-year survival rates for advanced GI-NET and lung epNET are 68% and 55%, respectively. NET can also start in the pancreas as pNET. While less common, pNET can be more aggressive and the five-year survival rate for advanced pNET is only 23%.

PDIGREE is a phase 3 trial led by The Alliance that is enrolling 1,046 intermediate- or poor-risk advanced RCC patients who have a clear cell component in their tumors. All patients are initially treated with up to 4 cycles of induction ipilimumab combined with nivolumab. Subsequently, patients are treated based on their response to the induction therapy. Patients achieving a complete response (CR) continue on maintenance nivolumab, while patients with progressive disease (PD) are switched to cabozantinib monotherapy. Patients who neither achieve a CR nor develop PD during induction are randomized 1:1 to either maintenance nivolumab or nivolumab in combination with cabozantinib 40 mg daily. The primary endpoint is OS, while PFS, CR rate, ORR and safety are among the secondary endpoints.

Pipeline Development Programs - Advancing Exelixis' Future Cancer Therapy Candidates

To continue growing our pipeline, we are investing heavily in the identification, exploration and advancement of new molecules that are clinically differentiated with the potential to improve the standard of care for cancer patients. Several product candidates have progressed into clinical trials, including both small molecules and biotherapeutics that we have discovered or in-licensed and believe have the potential to treat a variety of cancers. Below are summaries of our current and planned clinical development activities outside of the cabozantinib franchise.

Zanzalintinib Development Program

Zanzalintinib is a novel, potent, third-generation oral TKI that targets VEGF receptors, MET and the TAM kinases (TYRO3, AXL and MER) implicated in cancer's growth and spread, and is our first in-house compound to enter the clinic following our re-initiation of drug discovery activities in 2017. Zanzalintinib has a pharmacokinetic half-life of approximately one day, supporting once-daily dosing, which could translate into more effective management of adverse events and a potentially favorable safety profile compared with other VEGF-receptor TKIs. Taken together with the promising anti-tumor activity, we believe zanzalintinib is positioned to be a best-in-class VEGF-receptor TKI in a wide range of solid tumors when used as a monotherapy, as well as in combination regimens. Accordingly, we are evaluating zanzalintinib in a growing development program that builds on our prior experience with cabozantinib and targets indications with high unmet need. Beyond our established collaborations, we will continue to explore additional opportunities for novel combinations with zanzalintinib.

STELLAR-001 - Advanced Solid Tumors. Initiated in 2019, STELLAR-001 is a multicenter phase 1b/2 clinical trial evaluating the pharmacokinetics, safety, tolerability and preliminary anti-tumor activity of zanzalintinib and is divided into dose-escalation and expansion phases designed to evaluate zanzalintinib both as a monotherapy and in combination with atezolizumab in a variety of solid tumors. We previously presented data from STELLAR-001 during poster sessions at the 2022 ESMO Congress, which demonstrated preliminary clinical activity similar to that observed with cabozantinib, across a range of solid tumors and dose levels, with a manageable safety profile. The phase 2 recommended dose for both monotherapy zanzalintinib and zanzalintinib in combination with atezolizumab was determined to be 100 mg once daily. Enrollment into the STELLAR-001 expansion cohorts for clear cell RCC, nccRCC, hormone-receptor positive breast cancer, mCRPC and CRC is complete, and we presented initial results evaluating monotherapy zanzalintinib in patients with previously treated clear cell RCC during the Oral Abstracts session at the International Kidney Cancer Symposium (IKCS) in

November 2023. At a median follow-up time of 8.3 months, the findings demonstrated an ORR of 38% per RECIST v. 1.1 for the entire clear cell RCC cohort of 32 patients, including an ORR of 57% among the 14 patients who were not previously treated with cabozantinib; the disease control rate was 88%. The ORR for the 26 patients who had received prior VEGF receptor-TKIs was 35%, including responses in four of the 17 patients (24%) who had received prior cabozantinib. Preliminary results from a randomized expansion cohort of patients with metastatic CRC (n=107) from STELLAR-001 were presented at the ASCO GI 2025. In the overall population, all efficacy parameters, ORR, PFS and OS, favored the combination of atezolizumab plus zanzalintinib versus zanzalintinib monotherapy (PFS HR 0.65 (95% CI, 0.42-0.99); OS HR 0.89 (95% CI, 0.56-1.42)). With median follow up times of approximately 19 months for both arms, the ORR was 7.4% vs. 1.9%. In a subgroup analysis of patients without liver metastases (n=17 in each arm), ORR, PFS and OS also favored the combination of atezolizumab plus zanzalintinib versus zanzalintinib monotherapy (PFS HR 0.37 (95% CI, 0.15-0.91); OS HR 0.74 (95% CI, 0.27-2.04)). In this subgroup, the ORR was 17.6% vs 5.9%. We continue to be encouraged by zanzalintinib's emerging tolerability and activity profile, both as a monotherapy and in combination with ICIs.

STELLAR-002 - Advanced Solid Tumors. In December 2021, we initiated STELLAR-002, a multicenter phase 1b/2 clinical trial evaluating the safety, tolerability and efficacy of zanzalintinib in combination with either nivolumab, nivolumab and ipilimumab, or a fixed-dose combination of nivolumab and relatlimab, a lymphocyte activation gene-3-blocking (LAG-3) antibody developed by BMS. STELLAR-002 is divided into dose-escalation and expansion phases. We have established recommended doses of zanzalintinib for these combination regimens and are exploring them in a diverse array of solid tumor expansion cohorts, including clear cell RCC, nccRCC, HCC, mCRPC and CRC. The key efficacy endpoints are investigator-assessed ORR per RECIST v. 1.1, PFS and OS. Monotherapy zanzalintinib may also be evaluated to support regulatory requirements for dosing and contribution of components. We anticipate initial clinical data readouts from STELLAR-002 in the first half of 2025.

STELLAR-009 - Advanced Clear Cell RCC and Other Solid Tumors. In December 2023, we initiated STELLAR-009, a targeted phase 1b/2 trial evaluating the safety, tolerability and pharmacokinetics of zanzalintinib in combination with AB521, an inhibitor of hypoxia-inducible factor-2 alpha (HIF-2α) developed by Arcus Biosciences, Inc. (Arcus). In September 2024, we halted enrollment following the joint decision between us and Arcus to wind down the study and end our clinical collaboration given the two companies' differing strategies with respect to potential TKI-HIF combination regimens to treat RCC.

STELLAR-303 - CRC. In June 2022, we initiated STELLAR-303, a global, multicenter, randomized, open-label phase 3 pivotal trial evaluating zanzalintinib in combination with atezolizumab versus regorafenib in patients with metastatic, refractory non-microsatellite instability-high or non-mismatch repair-deficient CRC. We announced completion of enrollment into STELLAR-303 in August 2024, and preliminary results are expected in the second half of 2025, dependent on study event rates. Patients are randomized 1:1 to the experimental arm of zanzalintinib in combination with atezolizumab or to the control arm of regorafenib. Under the amended trial protocol, the primary efficacy endpoint for STELLAR-303 is OS in those patients without liver metastases, followed by OS in the full intent-to-treat population. Additional key endpoints include investigator-assessed PFS, ORR and DOR per RECIST v. 1.1 in each population.

CRC is the third most common cancer and the third-leading cause of cancer-related deaths in the U.S. According to the American Cancer Society, approximately 154,000 new cases will be diagnosed in the U.S. and around 53,000 people will die from the disease in 2025. CRC is most frequently diagnosed among people aged 65-74 and is more common in men and those of non-Hispanic American Indian/Alaska Native descent. Nearly a quarter of CRC cases are diagnosed at the metastatic stage, at which point the five-year survival rate is just 15%. It has been estimated that approximately 40-52% of metastatic CRC cases exhibit a RAS mutation.

STELLAR-304 - Non-Clear Cell RCC. In December 2022, we initiated STELLAR-304, a global, multicenter, randomized, open-label phase 3 pivotal trial evaluating zanzalintinib in combination with nivolumab versus sunitinib in previously untreated patients with advanced nccRCC. The trial aims to enroll approximately 291 patients at approximately 173 sites globally by mid-2025. Patients are being randomized 2:1 to the experimental arm of zanzalintinib in combination with nivolumab or to the control arm of sunitinib, respectively. The primary efficacy endpoints for STELLAR-304 are BIRC-assessed PFS and ORR per RECIST v 1.1. The secondary efficacy endpoint is OS. Based on current enrollment status in the trial, the primary endpoint of PFS is expected to be available in the second half of 2025, dependent on study event rates.

Non-clear cell RCC represents about 25% of RCC cases. Many of the therapies approved for advanced nccRCC are predominately based on data from ccRCC studies because nccRCC tumors are histologically diverse and rare in occurrence with historically poor outcomes.

STELLAR-305 - Squamous Cell Cancers of the Head and Neck (SCCHN). In December 2023, we initiated STELLAR-305, a global, multicenter, randomized, double-blinded phase 2/3 pivotal trial evaluating zanzalintinib in combination with pembrolizumab, an anti-PD-1 ICI developed by Merck & Co., Inc. (Merck & Co.), versus monotherapy pembrolizumab in patients with previously untreated PD-L1-positive recurrent or metastatic SCCHN. The trial aims to enroll approximately 600 patients at approximately 215 sites globally and enrollment is ongoing. Patients will be randomized 1:1 to receive zanzalintinib in combination with pembrolizumab or placebo in combination with pembrolizumab. The primary efficacy endpoints for STELLAR-305 are BIRC-assessed PFS per RECIST v. 1.1 and OS. Secondary endpoints include investigator-assessed PFS per RECIST v. 1.1 and ORR and DOR per RECIST v. 1.1 as assessed by both BIRC and the investigator.

SCCHN comprises head and neck cancers that begin in the squamous cells that line the mucosal surfaces of the head and neck. Accounting for about 90% of all head and neck cancers, SCCHN is classified by its location: it can occur in the oral cavity, oropharynx, nasal cavity and paranasal sinuses, nasopharynx, larynx or hypopharynx. Approximately 50,000 new cases of SCCHN are diagnosed in the U.S. every year, and SCCHN is more common among men and people over the age of 50. Depending on the site of the cancer and level of metastases, the five-year survival rate for metastatic SCCHN ranges from 4-35%.

Beyond STELLAR-303, STELLAR-304 and STELLAR-305, we intend to initiate additional early-stage and pivotal trials evaluating zanzalintinib across a broad array of future potential indications, including STELLAR-311, a planned phase 3 pivotal trial evaluating zanzalintinib versus everolimus as a first oral therapy in patients with advanced NET, regardless of site of origin, which we anticipate will commence in the first half of 2025.

To further expand our exploration of the clinical potential of zanzalintinib, in October 2024, we announced our entry into a clinical development collaboration with MSD International Business GmbH, known as Merck within the United States and Canada (Merck) to evaluate zanzalintinib in combination with KEYTRUDA® (pembrolizumab) in SCCHN and in combination with WELIREG® (belzutifan), Merck's oral HIF-2α inhibitor, in RCC. Under the collaboration, Merck will supply KEYTRUDA for our ongoing phase 3 STELLAR-305 trial in SCCHN. In addition, Merck will sponsor a phase 1/2 trial and two phase 3 pivotal trials in RCC; Merck will fund one of these phase 3 studies, and we will co-fund the phase 1/2 study and the other phase 3 study, as well as supply zanzalintinib and cabozantinib. We maintain all global commercial and marketing rights to zanzalintinib.

XL309 Development Program

In September 2023, we entered into an exclusive global license agreement with Insilico Medicine US, Inc. and its affiliate, Insilico Medicine Hong Kong Limited, along with their parent company and certain other affiliated entities (individually and collectively referred to as Insilico). The agreement with Insilico grants us global rights to develop and commercialize XL309, a potentially best-in-class small molecule inhibitor of USP1, a synthetic lethal target in the context of BRCA-mutated tumors. XL309 is currently being evaluated in a phase 1 clinical trial to explore its pharmacokinetics, safety, tolerability and preliminary anti-tumor activity in patients with advanced solid tumors as a monotherapy and in combination with olaparib, PARP1/2 inhibitor, and enrollment is ongoing. XL309 has potential in patients whose tumors are no longer responsive to PARP inhibitors (PARPi), including ovarian, breast and prostate cancers. XL309 also has potential in combination with PARPi agents to deepen and prolong the response seen to PARPi, as well as to broaden the activity beyond that observed in patients with tumors that harbor a BRCA1/2 mutation. Exelixis plans to present data from the XL309 program at a scientific meeting in 2025. For more information on the Insilico license agreement, see "—Collaborations and Business Development Activities—Research Collaborations and In-licensing Arrangements."

ADU-1805 Development Program

In November 2022, we executed an exclusive option and license agreement and clinical development collaboration with Sairopa B.V. (Sairopa) providing us with the right to exclusively in-license ADU-1805, a clinical-stage and potentially best-in-class mAb developed by Sairopa that targets SIRPα. In February 2023, the FDA cleared the initial IND for ADU-1805 to evaluate the safety and pharmacokinetics of ADU-1805 in adults with advanced solid tumors. ADU-1805 is currently being evaluated in a phase 1 clinical trial to explore its pharmacokinetics, safety, tolerability and preliminary anti-tumor activity in patients with advanced or metastatic refractory solid tumors, and enrollment is ongoing. The ADU-1805 study includes plans to investigate the compound's potential in combination with approved ICIs, including pembrolizumab. For more information on the Sairopa option arrangement, see "—Collaborations and Business Development Activities—Research Collaborations and In-licensing Arrangements."

A complete listing of all ongoing trials can be found at www.ClinicalTrials.gov.

Termination of CBX-12 and XB002 Development Programs

In January 2024, we elected to terminate our collaboration agreement, executed in November 2022 with Cybrexa Therapeutics, LLC (Cybrexa), and relinquish all rights with respect to CBX-12 (alphalexTM exatecan), a clinical-stage, peptide-drug conjugate that utilizes Cybrexa's proprietary alphalex technology to enhance delivery of exatecan to tumor cells. In August 2024, we announced that we will discontinue the development of XB002, our tissue factor (TF) targeting ADC, as part of our portfolio prioritization efforts. Based on available data, the compound is unlikely to improve upon tisotumab vedotin or other competitor TF-targeting ADCs currently in development. We plan to disclose data from the phase 1 JEWEL-101 study, evaluating XB002 in advance solid tumors, at a later date. We plan to reallocate resources to new pivotal trials with zanzalintinib, advancing XL309 and our growing pipeline.

Expansion of the Exelixis Pipeline

Increasing the number of novel anti-cancer agents in our pipeline is essential to our overall strategy and business goals. We are working to expand our oncology product pipeline through drug discovery efforts, which encompass our diverse biotherapeutics and small molecule programs exploring multiple modalities and mechanisms of action. This approach provides a high degree of flexibility with respect to target selection and allows us to prioritize those targets that we believe have the greatest chance of yielding impactful therapeutics. As part of our strategy, our drug discovery activities have included and continue to include research collaborations, in-licensing arrangements and other strategic transactions that collectively incorporate a wide range of technology platforms and assets and increase our probability of success. As of the date of this Annual Report on Form 10-K, we expect to progress up to three new development candidates into preclinical development during 2025. We will continue to engage in pipeline expansion initiatives with the goal of discovering, acquiring and/or in-licensing promising investigational oncology assets and then further characterize and develop them utilizing our established preclinical and clinical development infrastructure.

Biotherapeutics Programs

We are advancing a variety of biotherapeutics that have the potential to become anti-cancer therapies, including bispecific antibodies and ADCs. ADCs in particular present a unique opportunity for new cancer treatments, given their capabilities to deliver anti-cancer drug payloads to targets with increased precision while minimizing impact on healthy tissues. We have established multiple research collaborations and in-licensing arrangements and entered into other strategic transactions, aimed at conserving capital and managing risks, that provide us with access to antibodies, binders, payloads and conjugation technologies, which are the components employed to generate next-generation ADCs or multispecific antibodies. In addition to the option deal with Sairopa, some of our active research collaborations for biotherapeutics programs include collaborations with:

- Adagene Inc. (Adagene), which is focused on using Adagene's SAFEbody™ technology to develop novel masked ADCs or other innovative biotherapeutics with potential for improved therapeutic index;
- Catalent, Inc. (Catalent), which is focused on the discovery and development of multiple ADCs using Catalent's proprietary SMARTag® site-specific bioconjugation technology; and
- Invenra, Inc. (Invenra), which is focused on the discovery and development of novel binders and multispecific antibodies for the treatment of cancer.

We have made significant progress under our research collaborations and in-licensing arrangements and believe we will continue to do so in 2025 and future years. For example, in August 2024, we announced the initiation of a phase 1 clinical trial evaluating XB010, both as a monotherapy and in combination with pembrolizumab, in patients with advanced solid tumors, following the FDA's acceptance of our IND application, and enrollment is ongoing. XB010 is our first ADC advanced internally and consists of an MMAE payload conjugated to a mAb targeting the tumor antigen 5T4. XB010 was constructed using Catalent's SMARTag site-specific bioconjugation platform, and its 5T4-targeting mAb was discovered in collaboration with Invenra.

As a direct result of these arrangements, we are advancing four biotherapeutics development candidates toward potential IND filings in 2025 and 2026: XB628, XB371, XB064 and XB033. XB628 is a bispecific antibody that targets PD-L1 and natural killer cell receptor group 2A (NKG2A), identified as key regulators of natural killer cell activity, and was discovered, in part, in collaboration with Invenra. XB371 is a next-generation TF-targeting ADC that consists of a topoisomerase inhibitor payload conjugated to a mAb targeting TF and was discovered, in part, in collaboration with Catalent.

XB064 is a high-affinity mAb that targets immunoglobin-like transcript 2 (ILT2), which is associated with resistance to PD-1 pathway inhibitors, with potential to combine broadly with our internal pipeline and approved immunotherapy agents, and was discovered, in part, in collaboration with Invenra. XB033 is an ADC targeting the tumor antigen IL13Rα2, and was discovered, in part, in collaboration with Invenra and Catalent. For additional information on these specific research collaborations and in-licensing arrangements related to our biotherapeutics programs, see "—Collaborations and Business Development Activities—Research Collaborations and In-licensing Arrangements."

Small Molecule Programs

Since its formation in 2000, our drug discovery group has advanced over 25 compounds to the IND-stage, either independently or with collaboration partners, and today we deploy our drug discovery expertise to advance small molecule programs toward and through preclinical development. These efforts are led by our experienced scientists, including some of the same scientists who led the efforts to discover cabozantinib, cobimetinib and esaxerenone, each of which are now commercially distributed drug products. The furthest along of our internally-discovered small molecule product candidates is zanzalintinib, which is now being evaluated in phase 3 clinical trials, followed by XL495, which is being evaluated in a phase 1 clinical trial. We also augment our small molecule discovery activities through research collaborations and in-licensing arrangements. An example of this is XL309, in-licensed from Insilico and currently being evaluated in a phase 1 clinical trial. For additional information on our development plans for XL309, see "Exelixis Development Programs—Pipeline Development Programs – Advancing Exelixis' Future Cancer Therapy Candidates—XL309 Development Program" and for additional information on our research collaborations and in-licensing arrangements related to our small molecule programs, see "—Collaborations and Business Development Activities—Research Collaborations and In-licensing Arrangements." We also continue to make progress on multiple lead optimization programs for inhibitors of a variety of targets that we believe play significant roles in tumor growth, and we anticipate that some of these other programs could reach development candidate status in 2025 and beyond.

Collaborations and Business Development Activities

We have established multiple collaborations with leading biopharmaceutical companies for the commercialization and further development of the cabozantinib franchise, as well as research collaborations and in-licensing arrangements to enhance our early-stage pipeline and expand our ability to discover novel therapies.

Under our commercial collaborations, we are entitled to receive milestones and royalties or, in the case of cobimetinib, royalties from sales outside the U.S. and a share of profits (or losses) from commercialization in the U.S. Under our research collaborations and in-licensing arrangements, we are obligated to pay milestones and royalties to our various partners.

Cabozantinib Commercial Collaborations

Ipsen Collaboration

In February 2016, we entered into a collaboration and license agreement with Ipsen for the commercialization and further development of cabozantinib. Under the collaboration agreement, Ipsen received exclusive commercialization rights for current and potential future cabozantinib indications outside of the U.S., Canada and Japan. The collaboration agreement has been subsequently amended on multiple occasions, including in December 2016 to include commercialization rights in Canada. We have also agreed to collaborate with Ipsen on the development of cabozantinib for current and potential future indications. The parties' efforts are governed through a joint steering committee and appropriate subcommittees established to guide and oversee the collaboration's operation and strategic direction; however, we retain final decision-making authority with respect to cabozantinib's ongoing development.

In consideration for the exclusive license and other rights contained in the collaboration agreement, including commercialization rights in Canada, Ipsen paid us aggregate upfront payments of $210.0 million in 2016. As of December 31, 2024, we achieved aggregate milestone payments of $654.2 million related to regulatory and commercial progress by Ipsen since the inception of the collaboration agreement, including (a) a commercial milestone payment during 2024 for $150.0 million based on Ipsen achieving $600 million in cumulative net sales of cabozantinib in its related license territory over four consecutive quarters; (b) a CAD$3.0 million commercial milestone payment from Ipsen upon its achievement of CAD$30.0 million in cumulative net sales of cabozantinib over four consecutive quarters in Canada; and, (c) a $12.5 million regulatory milestone payment from Ipsen upon submission of a variation application to the EMA for evaluating cabozantinib versus placebo in patients with either advanced pNET or advanced epNET who experienced progression after prior systematic therapy.

We are also eligible to receive future development and regulatory milestone payments from Ipsen, totaling an aggregate of $7.0 million upon additional approvals of cabozantinib in future indications and/or jurisdictions, as well as contingent payments of up to $200.0 million and CAD$23.5 million associated with future sales milestones. We will further receive royalties on net sales of cabozantinib by Ipsen outside of the U.S. and Japan. We are entitled to receive a tiered royalty of 22% to 26% on annual net sales, with separate tiers for Canada; these 22% to 26% royalty tiers reset each calendar year. As of December 31, 2024, we have earned royalties of $671.9 million on net sales of cabozantinib by Ipsen since the inception of the collaboration agreement.

We received notification that, effective January 1, 2021, Royalty Pharma plc (Royalty Pharma) acquired from GlaxoSmithKline (GSK) all rights, title and interest in royalties on total net sales of any product containing cabozantinib for non-U.S. markets for the full term of the royalty and for the U.S. market through September 2026, after which time U.S. royalties will revert back to GSK. Accordingly, and consistent with our historical agreement with GSK, we are required to pay a 3% royalty to Royalty Pharma on total net sales of any product containing cabozantinib, including net sales by Ipsen.

We are responsible for funding cabozantinib-related development costs for those trials in existence at the time we entered into the collaboration agreement with Ipsen; global development costs for additional trials are shared between the parties, with Ipsen reimbursing us for 35% of such costs, provided Ipsen chooses to opt into such trials. In accordance with the collaboration agreement, Ipsen has opted into and is co-funding certain clinical trials, including: CheckMate -9ER, COSMIC-021, COSMIC-311, COSMIC-312, CONTACT-01, CONTACT-02 and CABINET.

We remain responsible for manufacturing and supply of cabozantinib for all development and commercialization activities under the collaboration agreement. We entered into a supply agreement with Ipsen to supply finished and labeled drug product for distribution in the territories outside of the U.S. and Japan for the term of the collaboration agreement as well as a quality agreement that provides respective quality responsibilities for the aforementioned supply. At the time we entered into the collaboration agreement, the parties also entered into a pharmacovigilance agreement, which defines each partner's responsibilities for safety reporting. The pharmacovigilance agreement requires us to maintain the global safety database for cabozantinib. To meet our obligations to regulatory authorities for the reporting of safety data from territories outside of the U.S. and Japan from sources other than our sponsored global clinical development trials, we rely on data collected and reported to us by Ipsen.

Unless earlier terminated, the collaboration agreement has a term that continues, on a product-by-product and country-by-country basis, until the later of (1) the expiration of patent claims related to cabozantinib, (2) the expiration of regulatory exclusivity covering cabozantinib or (3) ten years after the first commercial sale of cabozantinib, other than COMETRIQ. The supply agreement will continue in effect until expiration or termination of the collaboration agreement. The collaboration agreement may be terminated for cause by either party based on uncured material breach of either the collaboration agreement or the supply agreement by the other party, bankruptcy of the other party or for safety reasons. We may terminate the collaboration agreement if Ipsen challenges or opposes any patent covered by the collaboration agreement. Ipsen may terminate the collaboration agreement if the FDA or EMA orders or requires substantially all cabozantinib clinical trials to be terminated. Ipsen also has the right to terminate the collaboration agreement on a region-by-region basis after the first commercial sale of cabozantinib in advanced RCC in the given region. Upon termination by either party, all licenses granted by us to Ipsen will automatically terminate, and, except in the event of a termination by Ipsen for our material breach, the licenses granted by Ipsen to us shall survive such termination and shall automatically become worldwide, or, if Ipsen were to terminate only for a particular region, then for the terminated region. Following termination by us for Ipsen's material breach, or termination by Ipsen without cause or because we undergo a change of control by a party engaged in a competing program, Ipsen is prohibited from competing with us for a period of time.

Takeda Collaboration

In January 2017, we entered into a collaboration and license agreement with Takeda, as subsequently amended to, among other things, modify the amount of reimbursements we receive for costs associated with our required pharmacovigilance activities and milestones we are eligible to receive, as well as modify certain cost sharing obligations related to the Japan-specific development costs associated with CONTACT-01 and CONTACT-02. Under the collaboration agreement, Takeda has exclusive commercialization rights for current and potential future cabozantinib indications in Japan, and the parties have agreed to collaborate on the clinical development of cabozantinib in Japan. The operation and strategic direction of the parties' collaboration is governed through a joint executive committee and appropriate subcommittees.

In consideration for the exclusive license and other rights contained in the collaboration agreement, we received an upfront payment of $50.0 million from Takeda in 2017. As of December 31, 2024, we have also achieved aggregate milestone payments of $138.0 million related to regulatory and commercial progress by Takeda since the inception of the collaboration agreement. We are eligible to receive additional regulatory and development milestone payments, without limit, for additional potential future indications.

We are further eligible to receive commercial milestones, including milestone payments earned for the first commercial sale of a product of $108.0 million. We also receive royalties on the net sales of cabozantinib in Japan. We are entitled to receive a tiered royalty of 15% to 24% on the initial $300.0 million of net sales, and following this initial $300.0 million of net sales, we are then entitled to receive a tiered royalty of 20% to 30% on annual net sales thereafter; these 20% to 30% royalty tiers reset each calendar year. As of December 31, 2024, we have earned royalties of $47.1 million on net sales of cabozantinib by Takeda since the inception of the collaboration agreement.

Consistent with our historical agreement with GSK, we are required to pay a 3% royalty to Royalty Pharma on total net sales of any product containing cabozantinib, including net sales by Takeda.

Except for CONTACT-01 and CONTACT-02, Takeda is responsible for 20% of the costs associated with the cabozantinib development plan's current and future trials, provided Takeda opts into such trials, and 100% of costs associated with the cabozantinib development activities that are exclusively for the benefit of Japan. In accordance with the collaboration agreement, Takeda has opted into and is co-funding certain clinical trials, including: CheckMate -9ER; certain cohorts of COSMIC-021; CONTACT-01; and CONTACT-02.

Under the collaboration agreement, we are responsible for the manufacturing and supply of cabozantinib for all development and commercialization activities under the collaboration agreement. We entered into a clinical supply agreement covering the supply of cabozantinib to Takeda for the term of the collaboration agreement, as well as a quality agreement that provides respective quality responsibilities for the aforementioned supply. At the time we entered into the collaboration agreement, the parties also entered into a safety data exchange agreement, which defines each partner's responsibility for safety reporting. This agreement requires us to maintain the global safety database for cabozantinib. To meet our obligations to regulatory authorities for the reporting of safety data from Japan from sources other than our sponsored global clinical development trials, we rely on data collected and reported to us by Takeda.

Unless earlier terminated, the collaboration agreement has a term that continues, on a product-by-product basis, until the earlier of (1) two years after first generic entry with respect to such product in Japan or (2) the later of (A) the expiration of patent claims related to cabozantinib and (B) the expiration of regulatory exclusivity covering cabozantinib in Japan. The collaboration agreement may be terminated for cause by either party based on uncured material breach by the other party, bankruptcy of the other party or for safety reasons. We may terminate the agreement if Takeda challenges or opposes any patent covered by the collaboration agreement. After the commercial launch of cabozantinib in Japan, Takeda may terminate the collaboration agreement upon twelve months' prior written notice following the third anniversary of the first commercial sale of cabozantinib in Japan. Upon termination by either party, all licenses granted by us to Takeda will automatically terminate, and the licenses granted by Takeda to us shall survive such termination and shall automatically become worldwide.

Cabozantinib Development Collaborations

BMS Collaboration

In February 2017, we entered into a clinical trial collaboration agreement with BMS for the purpose of exploring the therapeutic potential of cabozantinib in combination with BMS's ICIs, nivolumab and/or ipilimumab, to treat a variety of types of cancer.

Under the collaboration agreement with BMS, each party granted to the other a non-exclusive, worldwide (within the collaboration territory as defined in the collaboration agreement and its supplemental agreements), non-transferable, royalty-free license to use the other party's compounds in the conduct of each clinical trial. The parties' efforts are governed through a joint development committee established to guide and oversee the collaboration's operation. Each trial is conducted under a combination IND application, unless otherwise required by a regulatory authority. Each party is responsible for supplying finished drug product for the applicable clinical trial, and responsibility for the payment of costs for each such trial will be determined on a trial-by-trial basis. Following the FDA's approval of CABOMETYX in combination with nivolumab as a first-line treatment of patients with advanced RCC, we and BMS commenced the commercial launch of the combination and have agreed to pursue commercialization and marketing efforts independently.

Roche Collaboration

In February 2017, we entered into a master clinical supply agreement with Roche for the purpose of evaluating cabozantinib and Roche's ICI, atezolizumab, in locally advanced or metastatic solid tumors. Under this agreement, in June 2017, we initiated COSMIC-021 and in December 2018, we initiated COSMIC-312. We were the sponsor of both trials, and Roche provided atezolizumab free of charge. Building upon encouraging clinical activity observed in COSMIC-021, in December 2019 we entered into a joint clinical research agreement with Roche to further evaluate the combination of cabozantinib with atezolizumab in patients with locally advanced or metastatic solid tumors, including in the CONTACT-01, CONTACT-02 and CONTACT-03 studies. A party to the joint clinical research agreement that proposes any additional combined therapy trials beyond any ongoing phase 3 pivotal trials must notify the other party and if agreed to, such additional combined therapy trial will become part of the collaboration; if not agreed to, the proposing party may conduct such additional combined therapy trial independently, subject to specified restrictions set forth in the joint clinical research agreement.

Under the joint clinical research agreement, each party granted to the other a non-exclusive, worldwide (excluding, in our case, territory already the subject of a license by us to Takeda), non-transferable, royalty-free license, with a right to sublicense (subject to limitations), to use the other party's intellectual property and compounds solely as necessary for the party to perform its obligations under the joint clinical research agreement. The parties' efforts are governed through a joint steering committee established to guide and oversee the collaboration and the conduct of the combined therapy trials. Each party is responsible for providing, and bearing the cost of, clinical supply for all combined therapy trials. Clinical trial expenses for each jointly conducted combined therapy trial are shared equally between the parties, and for each additional combined therapy trial not agreed to be conducted jointly, are borne by the proposing party, except that the cost of clinical supply for all combined therapy trials are borne by the party that owns the applicable product.

Unless earlier terminated, the joint clinical research agreement provides that it will remain in effect until the completion of all combined therapy trials under the collaboration, the delivery of all related trial data to both parties, and the completion of any then agreed-upon additional analyses. The joint clinical research agreement may be terminated for cause by either party based on any uncured material breach by the other party, bankruptcy of the other party or for safety reasons. Upon termination by either party, the licenses granted to each party will terminate upon completion of any ongoing activities under the joint clinical research agreement.

Zanzalintinib Clinical Collaborations

We have also entered into multiple collaboration and supply agreements to evaluate zanzalintinib in various combination trials, including with Roche's atezolizumab, BMS' nivolumab, ipilimumab and relatlimab and Merck's pembrolizumab and belzutifan. These agreements facilitate the efficient exploration of the tolerability and activity of zanzalintinib in combinations with a variety of established cancer therapies as we continue to build a broad development program for zanzalintinib. For descriptions of our ongoing clinical trials evaluating zanzalintinib in combination with other therapies, see "—Exelixis Development Programs—Pipeline Development Programs — Advancing Exelixis' Future Cancer Therapy Candidates—Zanzalintinib Development Program."

Research Collaborations and In-licensing Arrangements

As part of our pipeline expansion efforts, we have entered several research collaborations and in-licensing arrangements, as well other strategic transactions that collectively incorporate a wide range of technology platforms and assets and increase our probability of success. More recently, we have focused our business development activities on late preclinical and early-stage clinical assets that align with our oncology drug development, regulatory and commercial expertise, and that have potential as product candidates to treat cancer patients, including the following:

- Sairopa. In November 2022, we entered into an exclusive option and license agreement and clinical development collaboration with Sairopa to develop ADU-1805. Under the agreement, we made an upfront payment to Sairopa, including additional payments for near-term milestones, in exchange for an option to obtain an exclusive, worldwide license to develop and commercialize ADU-1805 and other anti-SIRPα antibodies, and for certain expenses to be incurred by Sairopa in conducting prespecified phase 1 clinical studies of ADU-1805 during the option period. Sairopa is eligible to receive additional development milestone payments during the option period. Following the completion of the prespecified clinical studies, we have the right to exercise our option upon payment of an option exercise fee. Upon option exercise, Sairopa will be eligible to receive additional development and commercial milestone payments, as well as royalties on potential sales.

- Insilico. In September 2023, we entered into an exclusive global license agreement with Insilico. Under the agreement, Insilico granted us global rights to develop and commercialize XL309 in exchange for an upfront payment to Insilico of $80 million. Insilico is also eligible to receive future development, commercial, and sales-based milestone payments, as well as tiered royalties on net sales. In the fourth quarter of 2023, we completed the transfer of stewardship of the ongoing phase 1 clinical trial evaluating XL309 from Insilico to us.

We continue to make progress on our various research collaborations and in-licensing arrangements focused on our early-stage pipeline with the goal of advancing new candidates toward the clinic, including the following:

- Catalent. In September 2020, we entered into a collaboration and license agreement with Catalent to develop multiple ADCs using Catalent's proprietary SMARTag site-specific bioconjugation technology. Under the September 2020 agreement, we made an upfront payment in exchange for an exclusive option to license up to four targets using Catalent's ADC platform over a three-year period. In addition, in August 2022 we exercised our right to extend the target selection term to five years and nominate up to two additional targets for an additional payment. For each option we decide to exercise, we will be required to pay an exercise fee, and will then assume responsibility for all subsequent clinical development, manufacturing and commercialization for that program. Catalent would then become eligible for potential development, regulatory and commercial milestone payments, as well as royalties on potential sales. We have also committed to contribute research funding to Catalent for discovery and preclinical development work. In December 2024, we terminated a separate license agreement with Catalent, previously entered into in November 2022, for three target programs.
- Adagene. In February 2021, we entered into a collaboration and license agreement with Adagene to utilize Adagene's SAFEbody technology platform to generate masked versions of mAbs from our growing preclinical pipeline for the development of ADCs or other innovative biotherapeutics against Exelixis-nominated targets. Under the agreement, we made an upfront payment in exchange for an exclusive, worldwide license to develop and commercialize any potential ADC products generated in collaboration with Adagene with respect to an initial target, as well as a second target we may nominate during the collaboration term. For each target that we nominate, we would then assume responsibility for all subsequent clinical development, manufacturing and commercialization for that program. Adagene is eligible for potential development, regulatory and commercial milestone payments, as well as royalties on potential sales.
- Iconic. In May 2019, we entered into an exclusive option and license agreement with Iconic to advance an innovative next-generation ADC program for cancer, leveraging Iconic's expertise in targeting TF in solid tumors. We later amended this agreement to obtain broad rights to develop the in-licensed anti-TF antibodies, allowing us to advance preclinical development of XB371, an ADC consisting of a topoisomerase payload conjugated to a TF-targeting monoclonal antibody.
- Invenra. In May 2018, we entered into a collaboration and license agreement with Invenra to discover and develop multispecific antibodies for the treatment of cancer. Invenra is responsible for antibody lead discovery and generation while we will lead IND-enabling studies, manufacturing, clinical development in single-agent and combination therapy regimens, and future regulatory and commercialization activities. The collaboration agreement provides that we will receive an exclusive, worldwide license to one preclinical, multispecific antibody asset, and that we will pursue multiple additional discovery projects across three different programs during the term of the collaboration. In October 2019, we expanded our collaboration to include the development of novel binders against six additional targets, which we can use to generate multispecific antibodies based on Invenra's B-Body™ technology platform, or with other platforms and formats at our option. We amended the agreement again in March 2020 and January 2021 to enable the use of target binders in non-Invenra platform-based modalities, such as ADC platforms, and to enable the development of biparatopic antibodies, respectively. Then in August 2021, we further expanded our collaboration to include up to 20 additional targets for biotherapeutics discovery and development, for which we agreed to pay Invenra exclusivity payments and research program funding over a three-year period. Under the collaboration, Invenra is eligible for project initiation fees and potential development, regulatory and commercial milestone payments, as well as tiered royalties on net sales of any approved products. We also have the right to exercise options with respect to certain of Invenra's other research programs in exchange for an option exercise payment, and Invenra is eligible for milestone payments and royalties for any products that arise from these optioned research programs.

In order to prioritize the advancement of our pipeline of clinical and near-clinical programs, we rebalanced our investment priorities and research and development resources toward our product development activities. Accordingly, in April 2024, we terminated our arrangements with Aurigene, BioInvent International AB, Cybrexa and STORM Therapeutics LTD.

Other Collaborations

Prior to the commercialization of our first product, COMETRIQ, our primary business strategy was focused on the development and out-licensing of innovative drug candidate compounds to pharmaceutical and biotechnology companies under collaboration agreements that allowed us to retain economic participation in the asset and support additional development of our proprietary products. Our collaboration agreements with Genentech and Daiichi Sankyo are representative of this historical strategy. Under our collaboration agreement with Genentech we out-licensed the further development and commercialization of COTELLIC, and under our collaboration agreement with Daiichi Sankyo we granted Daiichi Sankyo an exclusive, worldwide license to certain intellectual property, including MINNEBRO. We have since evolved and are now a fully integrated biopharmaceutical company focused on driving the expansion and depth of our product offerings through the continued development of the cabozantinib franchise and drug discovery efforts. While these historical collaboration agreements have the potential to provide future revenue, and while we have received some collaboration revenues from these arrangements, we do not expect to receive significant revenues from these historical collaboration agreements.

Manufacturing and Product Supply

We do not operate our own current Good Manufacturing Practice (GMP) manufacturing or distribution facilities for chemistry, manufacturing and control (CMC) development activities, preclinical, clinical or commercial production and distribution for our current products and new product candidates. Instead, we mostly rely on various third-party contract manufacturing organizations to conduct GMP manufacturing operations on our behalf. This external network consists of well-established and reputable global third-party GMP contract manufacturers for our CMC development and manufacturing that have good regulatory standing, suitable manufacturing capacities and capabilities. We will continue to expand this network as appropriate to meet our future commercial manufacturing and supply needs for our product candidates currently in development, should such programs advance to regulatory approval and subsequent commercialization. These third parties must comply with applicable legal and regulatory requirements, including the FDA's current GMP, the European Commission's (EC) Guidelines on Good Distribution Practice (GDP), as well as other stringent regulatory requirements enforced by the FDA or foreign regulatory agencies, as applicable, and are subject to routine inspections by such regulatory agencies. In addition, through our third-party contract manufacturers and data service providers, we continue to provide serialized commercial products as required to comply with the Drug Supply Chain Security Act (DSCSA) and its foreign equivalents where applicable.

Specifically with respect to CABOMETYX, we entered into agreements with secondary contract manufacturing organizations to produce additional commercial supplies of CABOMETYX tablets and cabozantinib drug substance, which bolsters our commercial supply chain and serves to mitigate the risk of supply chain interruptions or other failures.

We continually monitor and evaluate the performance of our third-party contract manufacturers on an ongoing basis for compliance with these requirements and to affirm their continuing capabilities to meet both our commercial and clinical needs. We also have contracted with a third-party logistics provider, with multiple distribution locations, to provide shipping and warehousing services for our commercial supply of both CABOMETYX and COMETRIQ in the U.S. We employ highly skilled personnel with both technical and manufacturing experience to diligently manage the activities at our third-party contract manufacturers and other supply chain partners, and our quality department audits them on a periodic basis.

We source raw materials that are used to manufacture our drug substance from multiple third-party suppliers in Asia, Europe and North America. Where appropriate, we stock sufficient quantities of these materials and provide them to our third-party drug substance contract manufacturers so they can manufacture adequate drug substance quantities per our requirements, for both clinical and commercial purposes. We store drug substance at third-party facilities and provide appropriate amounts to our third-party drug product contract manufacturers, who manufacture, package and label our specified quantities of finished goods for COMETRIQ and CABOMETYX. We also rely on our third-party contract manufacturers to source materials such as excipients, components and reagents, which are required to manufacture our drug substance and finished drug product.

We have established and continue to maintain substantial safety stock inventories for our drug substance and drug products, and we store these quantities in multiple locations. The quantities that we store are based on our business needs and take into account forecasts of global market demand, production lead times, potential supply interruptions and shelf life for our drug substance and drug products. We have not experienced significant production delays or seen significant impairment to our supply chain as a result of the ongoing geopolitical hostilities in Eastern Europe and the Middle East or other global events. We believe that our current manufacturing network has the appropriate capacity to produce sufficient

commercial quantities of CABOMETYX to support the currently approved RCC, HCC and DTC indications, and also potential additional indications if trials evaluating CABOMETYX in those indications are successful and gain regulatory approval. Our manufacturing footprint also enables us to fulfill our supply obligations for our products and product candidates to our collaboration partners for global commercial and development purposes.

Marketing and Sales

We have a fully integrated commercial team consisting of sales, marketing, market access, and commercial operations functions. Our sales team promotes CABOMETYX and COMETRIQ in the U.S. We market our products in the U.S. and concentrate our efforts on oncologists, oncology nurses, pharmacists and other healthcare professionals. In addition to using customary in-person pharmaceutical company practices, we also utilize digital marketing technologies to expand our engagement opportunities with customers.

Our commercial products, CABOMETYX and COMETRIQ, are sold initially through wholesale distribution and specialty pharmacy channels and then, if applicable, resold to hospitals and other organizations that provide CABOMETYX and COMETRIQ to end-user patients. To facilitate our commercial activities in the U.S., we also employ various third parties, such as advertising agencies, market research firms and vendors providing other sales-support related services as needed, including digital marketing and other non-personal promotion. We believe that our commercial team and distribution practices are sufficient to facilitate our marketing efforts in reaching our target audience and our delivery of our products to patients in a timely and compliant fashion.

In addition, we rely on Ipsen and Takeda for ongoing and further commercialization and distribution of CABOMETYX in territories outside of the U.S., as well as for access and distribution activities for the approved products, including named patient use programs or similar programs, and we also rely on Ipsen for these same activities with respect to the commercialization and distribution of COMETRIQ outside of the U.S.

To help ensure that all eligible patients in the U.S. have appropriate access to CABOMETYX and COMETRIQ, we have established a comprehensive reimbursement and patient support program called Exelixis Access Services (EASE). Through EASE, we provide co-pay assistance to qualified, commercially insured patients to help minimize out-of-pocket costs and provide free drug to uninsured or underinsured patients who meet certain clinical and financial criteria. In addition, EASE provides comprehensive reimbursement support services, such as prior authorization assistance, benefits investigation and, if needed, appeals support. Beyond financial assistance, patients who participate in EASE also receive treatment coordination through a dedicated case manager, as well as clinical outreach and support from a network of oncology nurses or other healthcare professionals who help many of these patients better understand how to take their medication and mitigate side effects.

Environmental, Health and Safety

Our research and development processes involve the controlled use of certain hazardous materials and chemicals. In the U.S., at the federal, state and local levels, and in other foreign countries, we are subject to environmental, health and workplace safety laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous materials. While we have incurred, and will continue to incur, expenditures to maintain compliance with these laws and regulations, we do not expect the cost of complying with these laws and regulations to be material.

Many of our employees work in our on-site laboratory facilities and are trained on chemical hygiene, the use of personal protective equipment and other relevant laboratory safety topics, including working with blood-borne pathogens. Current staff are retrained regularly. We also extend these trainings to facilities staff and others who support our work in the labs. To maintain a safe environment for all staff, we have established a Lab Safety Committee to oversee the working conditions in our laboratory and office environments and conduct regular safety inspections, with reports provided to our Ethics Committee on a regular basis. We regularly perform thorough safety inspections of our laboratories, and continuously update our procedures based on the observations made during these inspections. Additionally, we conduct periodic industrial hygiene monitoring to ensure lab staff working with certain known hazardous chemicals do not exceed regulated exposure limits, regularly test and certify fume hoods, biosafety cabinets and other individual pieces of equipment on which employees rely to maintain a safe working environment. We also adhere to the standards set by the Environmental Protection Agency, the Occupational Safety and Health Administration, Cal-OSHA and Bay Area Air Quality Management District, among other governing bodies, to ensure compliance with laws and regulations and help keep our employees safe.

Government Regulation

Clinical Development

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, manufacture and marketing of pharmaceutical products. These agencies and other federal, state and local entities regulate, among other things, research and development activities and the testing, marketing approval, manufacture, quality control, safety, effectiveness, labeling, storage, distribution, post-marketing safety reporting, export, import, record keeping, advertising and promotion of our products.

The process required by the FDA before product candidates may be marketed in the U.S. generally involves the following:

- nonclinical laboratory and animal tests, some of which must be conducted in accordance with Good Laboratory Practices;
- submission of an IND, which contains results of nonclinical studies (e.g., laboratory evaluations of the chemistry, formulation, stability and toxicity of the product candidate), together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, and must become effective before human clinical trials may begin;
- approval by an independent institutional review board or ethics committee for each clinical trial site before each trial may be initiated;
- adequate and well-controlled human clinical trials conducted in accordance with the protocol, IND and Good Clinical Practice (GCP) to establish the safety and efficacy of the product candidate for its proposed intended use;
- for drug products, submission of a New Drug Application (NDA) to the FDA for commercial marketing, or generally of a supplemental New Drug Application (sNDA), for approval of a new indication if the product is already approved for another indication;
- for biotherapeutic products, submission of a Biologics License Application (BLA) to the FDA for commercial marketing, or generally a supplemental Biologics License Application (sBLA) for approval of a new indication if the product is already approved for another indication;
- pre-approval inspection of manufacturing facilities and selected clinical investigators, clinical trial sites and/or Exelixis as the clinical trial sponsor for their compliance with GMP and GCP, respectively;
- payment of user fees for FDA review of an NDA or BLA unless a fee waiver applies;
- agreement with the FDA on the final labeling for the product and design and implementation of any required Risk Evaluation and Mitigation Strategy;
- if the FDA convenes an advisory committee, satisfactory completion of the advisory committee review; and
- FDA approval of the NDA or sNDA, or BLA or sBLA.

For purposes of NDA approval, human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1 studies, which involve the initial introduction of a new drug product candidate into humans, are initially conducted in a limited number of subjects to test the product candidate for safety, tolerability, absorption, metabolism, distribution and excretion in healthy humans or patients. In rare cases, a Phase 1 study that is designed to assess effectiveness may serve as the basis for FDA marketing approval of a drug or for a label expansion. For instance, at the FDA's discretion, a product may receive approval based on a Phase 1b study if effectiveness results from the study are extremely compelling, approval of the drug would address a significant unmet patient need, and the drug is being approved through the accelerated approval pathway. As discussed below, accelerated approval generally requires at least one post-approval study to confirm clinical benefit.
- Phase 2 studies are conducted with groups of patients afflicted with a specified disease in order to provide enough data to evaluate the preliminary efficacy, optimal dosage, and common short-term side effects and risks associated with the drug. Multiple phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive phase 3 clinical trials. Phase 2 studies are typically well controlled, closely monitored, and conducted in a relatively small number of patients, usually involving no more than several hundred subjects.

- Phase 3 studies are conducted to gather the additional information about effectiveness and safety across a higher number of patients and evaluate the overall benefit-risk relationship of the product candidate following earlier phase evaluations, which will have provided preliminary evidence suggesting an effective dosage range and acceptable safety profile for the product candidate. Phase 3 trials are also intended to provide an adequate basis for physician labeling of the product if it is approved.

The FDA may require, or companies may pursue, additional clinical trials after a product is approved. These so-called post-marketing or "phase 4" studies may be deemed a condition to be satisfied after a drug receives approval. Failure to satisfy such post-marketing commitments or requirements can result in FDA enforcement action, up to and including withdrawal of NDA approval.

FDA Review and Approval

For approval of a new drug or changes to the labeling of an approved drug, including new indications, the results of product development, preclinical studies and clinical trials are submitted to the FDA as part of an NDA or sNDA. The submission of an NDA requires payment of a substantial user fee to the FDA. The FDA may convene an advisory committee to provide clinical insight on NDA review questions, although the FDA is not required to follow the recommendations of an advisory committee. The FDA may initially issue a Refuse to File letter for an incomplete NDA or sNDA, or it may deny approval of an NDA or sNDA by way of a Complete Response letter if the applicable regulatory criteria are not satisfied, or alternatively require additional clinical and/or nonclinical data and/or an additional phase 3 pivotal clinical trial. Once issued, the FDA may withdraw product approval if ongoing regulatory standards are not met or if safety problems occur after the product reaches the market. Satisfaction of FDA development and approval requirements or similar requirements of state, local and foreign regulatory agencies typically takes several years, and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease. In particular, the FDA has developed and implemented, and continues to develop and implement, various guidance, programs and initiatives specific to oncology products that can affect product development and the data necessary for approval.

Any products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including obtaining prior FDA approval of certain changes to the approved NDA, record-keeping requirements, annual report submission, and reporting of adverse experiences with, and interruptions in the manufacture of, the drug. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies as well as list the products they manufacture. Thus, we and our third-party contract manufacturing organizations are subject to periodic unannounced inspections by the FDA and certain state agencies, as well as inspectors from other jurisdictions in which our products are approved, for compliance with GMP, which impose certain manufacturing requirements (including procedural and documentation requirements) upon us and our third-party contract manufacturing organizations.

In the U.S., the Orphan Drug Act of 1983, as amended, provides incentives for the development of drugs and biotherapeutic products for rare diseases or conditions that affect fewer than 200,000 people in the U.S. (or for which there is no reasonable expectation that the cost of developing and making available the drug in the U.S. for such disease or condition will be recovered from sales of the drug in the U.S.). Certain of the incentives turn on the drug first being designated as an orphan drug. To be eligible for designation as an orphan drug (Orphan Drug Designation), the drug must have the potential to treat such rare disease or condition as described above. In addition, the FDA must not have previously approved a drug considered the "same drug," as defined in the FDA's orphan drug regulations, for the same orphan-designated indication or the sponsor of the subsequent drug must provide a plausible hypothesis of clinical superiority over the previously approved same drug. Upon receipt of Orphan Drug Designation, the sponsor is eligible for tax credits of up to 25% for qualified clinical trial expenses and waiver of the PDUFA application fee. In addition, upon marketing approval, an orphan drug could be eligible for seven years of market exclusivity. Orphan drug exclusivity, if awarded, only blocks the approval of any drug considered the same drug for the same orphan indication. A subsequent same drug could break an approved drug's orphan exclusivity through a demonstration of clinical superiority.

Expedited FDA Approval Pathways

The FDA has various programs that are intended to expedite or simplify the process for developing and reviewing promising drugs, or to provide for the approval of a drug on the basis of a surrogate endpoint. Generally, drugs that are eligible for these programs are those for serious or life-threatening conditions, those with the potential to address unmet medical needs and those that offer meaningful benefits over existing treatments. Examples of such programs include fast

track designation, breakthrough therapy designation, priority review and accelerated approval, and the eligibility criteria of and benefits for each program vary:

- Fast track designation is a process designed to facilitate the development and expedite the review of drugs intended to treat serious or life-threatening diseases or conditions that demonstrate the potential to fill unmet medical needs, by providing, among other things, eligibility for accelerated approval if relevant criteria are met, and rolling review, which allows submission of individually completed sections of an NDA for FDA review before the entire submission is completed.
- Breakthrough therapy designation is a process designed to expedite the development and review of drugs that are intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. Drugs designated as breakthrough therapies can also be eligible for accelerated approval. The FDA will seek to ensure the sponsor of a breakthrough therapy product candidate receives intensive guidance on an efficient drug development program, intensive involvement of senior managers and experienced staff on a proactive, collaborative and cross-disciplinary review, and rolling review.
- Priority review is designed to shorten the review period for drugs that treat serious conditions and that, if approved, would offer significant advances in safety or effectiveness or would provide a treatment where no adequate therapy exists. Under priority review, the FDA aims to take action on the application within six months as compared to a standard review time of 10 months, from the 60-day filing date. Sponsors may also obtain a priority review voucher upon approval of an NDA for certain qualifying diseases and conditions that can be applied to a subsequent NDA submission, or sold to another sponsor.
- Accelerated approval provides for an earlier approval for a new drug that is intended to treat a serious or life-threatening disease or condition and that provides a meaningful advantage over available therapies and demonstrates an effect on a surrogate endpoint, or an intermediate clinical endpoint, which is considered reasonably likely to predict clinical benefit. As a condition of approval, the FDA requires that a sponsor of a product candidate receiving accelerated approval perform post-marketing clinical trials or provide data on established clinical endpoints from the same trial to confirm the clinical benefit as predicted by the surrogate marker trial. The FDA may require such required post-marketing clinical trials to be underway prior to approval, or within a specific period thereafter, and will specify the conditions for such trials. Sponsors must provide reports on post-marketing trial progress no later than 180 days after approval and every 180 days thereafter until such trials are completed. The failure to conduct required post-marketing trials with due diligence and/or to submit the required reports are prohibited acts, and these failures by sponsor in administering such trials, or the failure of such trials to confirm the clinically meaningful outcome, may result in withdrawal of the accelerated approval of the drug or the indication. The FDA can also withdraw a drug approved under accelerated approval on an expedited basis provided it follows certain procedures.

Specifically, with respect to oncology products, the FDA may review applications under the Real-Time Oncology Review (RTOR) program established by the FDA's Oncology Center of Excellence (OCE). The RTOR program, which allows an applicant to pre-submit components of the NDA or BLA to allow the FDA to review clinical data before the complete filing is submitted, aims to explore a more efficient review process to ensure that safe and effective treatments are available to patients as early as possible, while maintaining and improving review quality. Drugs considered for review under the RTOR program must be likely to demonstrate substantial improvements over available therapy, which may include drugs previously granted breakthrough therapy designation for the same or other indications and must have straight-forward study designs and endpoints that can be easily interpreted.

Abbreviated FDA Approval Pathways and Generic Products

The Drug Price Competition and Patent Term Restoration Act of 1984 (The Hatch-Waxman Act) established two abbreviated approval pathways for drug products in which potential competitors may take advantage of shortened development timelines by relying upon the FDA's prior approval of the same or similar drug product.

- Abbreviated New Drug Application (ANDA). An ANDA may be approved by the FDA if the applicant demonstrates that the proposed generic product is the same as the approved drug, which is referred to as the Reference Listed Drug (RLD). Generally, an ANDA must contain data and information showing that the proposed generic product and RLD (1) have the same active ingredient, in the same strength and dosage form, to be delivered via the same route of administration, (2) are intended for the same uses, and (3) are bioequivalent. This is instead of independently demonstrating the proposed product's safety and effectiveness through clinical development.

Conducting bioequivalence testing is generally less time consuming and costly than conducting a full set of clinical trials in humans. In this regard, the FDA has published draft product-specific guidance containing bioequivalence recommendations for development of generic drug products containing cabozantinib, the active pharmaceutical ingredient in CABOMETYX and COMETRIQ, as it does for many FDA-approved drug products.

- 505(b)(2) NDAs. An NDA under section 505(b)(2) (505(b)(2) NDA) of the Federal Food, Drug, and Cosmetic Act (FDCA) is an application for which one or more of the investigations relied upon by the applicant for approval were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. Under 505(b)(2) NDA, an applicant may rely, in part, on the FDA's previous approval of a listed drug, or published literature, in support of its application. If the 505(b)(2) NDA applicant establishes that reliance on the FDA's prior findings of safety and efficacy for an approved product is scientifically appropriate, it may eliminate the need to conduct certain preclinical or clinical studies. The FDA may require additional studies or measurements, including comparability studies.

Unlike a full NDA for which the sponsor has conducted or obtained a right of reference to all the data essential to approval, the filing of an ANDA or a 505(b)(2) NDA may be delayed due to patent or exclusivity protections covering the RLD or listed drug. The Hatch-Waxman Act provides (a) up to five years of exclusivity for the first approval of a new chemical entity (NCE) (NCE exclusivity) and (b) three years of exclusivity for approval of an NDA or sNDA for a product that is not an NCE but rather where the application contains new clinical studies conducted or sponsored by the sponsor and considered essential to the approval of the NDA or sNDA (three-year "changes" exclusivity). NCE exclusivity runs from the time of approval of the NDA and bars the FDA from accepting for review any ANDA or 505(b)(2) NDA for a drug containing the same active moiety for five years (or for four years if the application contains a Paragraph IV certification asserting that a patent listed in the Orange Book for the RLD or listed drug is invalid or not infringed by the ANDA/505(b)(2) NDA product). The three-year "changes" exclusivity generally bars the FDA from approving any ANDA or 505(b)(2) NDA application that relies on the information supporting the approval of the drug or the change to the drug for which the information was submitted and the exclusivity granted.

Both Congress and the FDA are considering, and have enacted, various legislative and regulatory proposals focused on drug competition, including legislation focused on drug patenting and provision of drug to generic applicants for testing. For example, the Ensuring Innovation Act, enacted in April 2021, amended the FDA's statutory authority for granting NCE exclusivity to reflect the agency's existing regulations and longstanding interpretation that award NCE exclusivity based on a drug's active moiety, as opposed to its active ingredient, which is intended to limit the applicability of NCE exclusivity, thereby potentially facilitating generic competition. In addition, the Further Consolidated Appropriations Act, 2020, which incorporated the framework from the Creating and Restoring Equal Access To Equivalent Samples (CREATES) legislation, allows ANDA, 505(b)(2) NDA or biosimilar developers to obtain access to branded drug and biotherapeutic product samples. Further, Section 3222 of the Consolidated Appropriations Act, 2023, enacted on December 29, 2022 (the 2023 Appropriations Act), requires the FDA to make therapeutic equivalence determinations for 505(b)(2) NDAs at the time of approval, or up to 180 days thereafter, if requested by the applicant.

Additionally, Section 3224 of the 2023 Appropriations Act allows the FDA to approve an ANDA even if there are differences between the generic drug's proposed labeling and that of the listed drug due to the FDA approving a change to the listed drug's label (excluding warnings) within 90 days of when the ANDA is otherwise eligible for approval, provided that the ANDA applicant agrees to submit revised labeling for the generic drug within 60 days of approval. Moreover, in September 2023, the U.S. Federal Trade Commission (FTC) issued a policy statement, supported by the FDA, warning brand pharmaceutical companies that they could face legal action under the FTC Act if they improperly list patents in the Orange Book, and the FTC subsequently initiated challenges against patents held by brand pharmaceutical companies and listed in the Orange Book under the FDA's patent listing dispute process.

Orange Book Listing. An NDA sponsor must identify to the FDA patents that claim the drug substance or drug product or approved method of using the drug. When the drug is approved, those patents are among the information about the product that is listed in the FDA publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the *Orange Book*. Any applicant who files an ANDA or a 505(b)(2) NDA must certify, for each patent listed in the Orange Book for the RLD that (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA, (2) such patent has expired, (3) the listed patent will expire on a particular date and approval is sought after patent expiration, or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. An ANDA or 505(b)(2) NDA applicant may also submit a statement that it intends to carve-out from the labeling of its product an RLD's use that is protected by exclusivity or a method of use patent. The fourth certification described above is known as a Paragraph IV certification. A notice of the Paragraph IV

certification must be provided to each owner of the patent that is the subject of the certification and to the reference NDA holder. The reference NDA holder and patent owners may initiate a patent infringement lawsuit in response to the Paragraph IV notice. Filing such a lawsuit within 45 days of the receipt of the Paragraph IV certification notice prevents the FDA from approving the ANDA or 505(b)(2) NDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA or 505(b)(2) NDA applicant. The ANDA or 505(b)(2) NDA also will not receive final approval until any applicable non-patent exclusivity listed in the Orange Book for the RLD has expired.

Regulatory Approval Outside of the United States

In addition to regulations in the U.S., we are subject to regulations of other countries governing clinical trials and the manufacturing, commercial sales and distribution of our products outside of the U.S. Whether or not we obtain FDA approval for a product, we must obtain approval by the comparable regulatory authorities of countries outside of the U.S. before we can commence clinical trials in such countries and approval of the regulators of such countries or economic areas, such as the EU, before we may market products in those countries or areas. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from place to place, and the time may be longer or shorter than that required for FDA approval.

The way clinical trials are conducted in the EU has undergone a major change with the application of Regulation (EU) 536/2014, repealing the existing Directive 2001/20/EC. This regulation harmonizes the assessment and supervision processes for clinical trials throughout the EU, via an EU portal and database, which the EMA will maintain in collaboration with the Member States and the EC. Following the EC's confirmation of full functionality of the Clinical Trials Information System (CTIS) through an independent audit, which was published in the Official Journal of the European Union in August 2021, Regulation (EU) 536/2014 became applicable concurrent with the CTIS "go-live" date on January 31, 2022. While existing clinical trials could continue to be conducted under the rules of Directive 2001/20/EC until January 31, 2025, any clinical trial initiated on or after January 31, 2023, must comply with the rules of the new regulation.

Under EU regulatory systems, a company may submit a marketing authorization application (MAA) either under centralized or decentralized procedure. Under the centralized procedure, MAAs are submitted to the EMA for scientific review by the Committee for Medicinal Products for Human Use (CHMP) so that an opinion is issued on product approvability. The opinion is considered by the EC which is responsible for granting the centralized marketing authorization in the form of a binding EC decision. If the application is approved, the EC grants a single marketing authorization that is valid for all EU Member States as well as Iceland, Liechtenstein, and Norway, collectively the European Economic Area. The decentralized and mutual recognition procedures, as well as national authorization procedure are available for products for which the centralized procedure is not compulsory. The mutual recognition procedure provides for the EU Member States selected by the applicant to mutually recognize a national marketing authorization that has already been granted by the competent authority of another Member State, referred to as the Reference Member State (RMS). The decentralized procedure is used when the product in question has yet to be granted a marketing authorization in any Member State. Under this procedure the applicant can select the Member State that will act as the RMS. In both the mutual recognition and decentralized procedures, the RMS reviews the application and submits its assessment of the application to the Member States where marketing authorizations are being sought, referred to as Concerned Member States. Within 90 days of receiving the application and assessment report, each Concerned Member State must decide whether to recognize the RMS assessment or reject it based on potential serious risk to public health. If the disputed points cannot be resolved, the matter is eventually referred to the Coordination Group on Mutual Recognition and Decentralized Procedures in the first instance to reach an agreement and failing to reach such an agreement, a referral to the EMA and the CHMP for arbitration that will result in an opinion to form the basis of a decision to be issued by the EC binding on all Member States. If the application is successful during the decentralized or mutual recognition procedure, national marketing authorizations will be granted by the competent authorities in each of the Member States chosen by the applicant.

Conditional marketing authorizations may be granted in the centralized procedure for a limited number of medicinal products for human use referenced in EU law applicable to conditional marketing authorizations where the clinical dataset is not comprehensive, if (1) the risk-benefit balance of the product is positive, (2) it is likely that the applicant will be in a position to provide the required comprehensive clinical trial data, (3) unmet medical needs will be fulfilled and (4) the benefit to public health of the immediate availability on the market of the medicinal product outweighs the risk inherent in the fact that additional data are still required.

As in the U.S., we may apply for designation of a product as an orphan drug for the treatment of a specific indication in the EU before the application for marketing authorization is made. In the EU, orphan designation is available

for products in development which are either: (a) intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than 5 in 10,000 persons in the EU; or (b) intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition affecting a larger number of persons but when, without incentives, it is unlikely that sales of the drug in the EU would be sufficient to justify the necessary investment in developing the medicinal product. Additionally, the sponsor of an application for designation of a product as an orphan drug in the EU must establish that there exists no satisfactory authorized method of diagnosis, prevention, or treatment of the condition or even if such treatment exists, the product will be of significant benefit to those affected by that condition.

Orphan drugs in the EU enjoy economic and marketing benefits, including up to ten years of market exclusivity for the approved indication unless another applicant for a similar medicinal product can show that its product is safer, more effective or otherwise clinically superior to the orphan-designated product. The period of market exclusivity may be reduced to six years if at the end of the fifth year it is established that the criteria for orphan designation are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

As part of the EU Pharmaceutical Strategy, the EC published a proposal for a comprehensive revision of the EU pharmaceutical legislation. If adopted by the European Parliament and the Council, the new legislation is likely to significantly change the regulatory regime applicable to both the "normal" data and market exclusivity and the orphan exclusivities and reduce/modulate the exclusivities and rewards that could be granted to medicinal products. In addition, the proposal envisages changes to the concept of unmet medical need and considers introducing novel rewards for orphan medicinal products addressing a high unmet medical need. The adoption of the new legislation is not expected before the second half of 2025 at the earliest and it will start to apply 18 months after the entry in force.

Healthcare and Data Privacy Regulation

Federal and state healthcare laws and regulations, including fraud and abuse and health information privacy and security laws, also govern our business. If we fail to comply with those laws, we could face substantial penalties and our business, results of operations, financial condition and prospects could be adversely affected. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute (AKS), which prohibits, among other things, knowingly and willfully, soliciting, receiving, offering or paying remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as Medicare and Medicaid;
- federal civil and criminal false claims laws and civil monetary penalty laws, such as the federal False Claims Act, which impose criminal and civil penalties and authorize civil whistleblower or qui tam actions, against individuals or entities for, among other things: knowingly presenting, or causing to be presented, to government, claims for payment that are false or fraudulent; making a false statement or record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government;
- the Health Insurance Portability and Accountability Act of 1996 (HIPAA), which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;
- HIPAA as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH), and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security, transmission and breach reporting of individually identifiable health information. Although pharmaceutical companies are not generally considered to be a covered entity or business associate under HIPAA, we could be subject to penalties if we use or disclose individually identifiable health information in a manner not authorized or permitted by HIPAA. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for

damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;

- the federal false statements statute, which prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the federal transparency requirements under the Patient Protection and Affordable Care Act of 2010, as amended (PPACA), often referred to as the Open Payments program, requires certain manufacturers to track and report to the Centers for Medicare & Medicaid Services (CMS) annually certain payments and other transfers of value provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners) and teaching hospitals, as well as ownership interests held by such physicians and their immediate family during the previous calendar year; and federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Additionally, we are subject to state law equivalents of each of the above federal laws, which may be broader in scope and apply regardless of whether the payer is a governmental healthcare program, and many of which differ from each other in significant ways and may not have the same effect, further complicate compliance efforts. Numerous federal and state laws, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, storage, transfer, security, use and disclosure of personal information. For example, the California Consumer Privacy Act of 2018, as amended (CCPA), went into operation in January 2020 and broadly defines personal information, affords California residents expanded privacy rights and protections and provides for civil penalties for violations and a private right of action related to certain data security breaches. These protections were expanded by the California Privacy Rights Act (CPRA). Legislators and regulators in other states are also imposing new data and security privacy laws and regulations, including new and greater monetary fines or penalties for privacy violations, that may impact our operations, including both comprehensive and sector specific legislation. Additionally, Congress is considering further federal privacy legislation. These obligations are quickly changing in an increasingly stringent fashion, and may create uncertainty as to how to comply and potentially require us to modify our policies and practices. The compliance process may be costly and may divert the attention of management and technical personnel. Our failure to comply with current and future laws could result in significant penalties, including, but not limited to: government enforcement actions, investigations and criminal and other proceedings; additional reporting requirements and/or oversight; bans on processing personal data; and orders to destroy or not use personal data. Failure to comply may also result in reputational harm and could have a material adverse effect on our business, including, but not limited to: interruptions or stoppages in our business operations, inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or restructuring of our operations. In addition, most healthcare professionals and facilities who may prescribe our products and from whom we may obtain patient health information, are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology and Clinical Health Act (HIPAA). Although we are not considered to be a covered entity or business associate under HIPAA with respect to our clinical and commercial activities, we could be subject to penalties if we use or disclose individually identifiable health information in a manner not authorized or permitted by HIPAA. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues with the potential to affect our business, including laws in all 50 states requiring security breach notification in some circumstances. The CCPA, as amended by the CPRA, HIPAA and these other laws could create liability for us or increase our cost of doing business. International laws, such as the EU General Data Protection Regulation 2016/679 (GDPR), could also apply to our operations. Failure to provide adequate privacy protections and maintain compliance with applicable privacy laws could jeopardize business transactions across borders and result in significant penalties.

In addition, we participate in the 340B Drug Pricing Program (the 340B Program), the Medicaid Drug Rebate Program (MDRP), and a number of other federal and state government pricing programs in the U.S. in order to obtain coverage for our products by certain government health care programs. Our participation in these programs generally requires us to make disclosures and to pay substantial rebates or offer our drugs at substantial discounts to certain purchasers (including "covered entities" purchasing under the 340B Program. Changes to our obligations under these government pricing programs occur frequently and program requirements are often ambiguous, and we cannot predict

how future guidance or rules would affect our profitability (including the potential for increases in our overall Medicaid rebate liability and the obligation to charge greatly reduced prices to covered entities). A discussion of risks and uncertainties that may affect our participation in the 340B Program is set forth in "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K.

We are also required to discount our products to authorized users of the Federal Supply Schedule of the General Services Administration, under which additional laws and requirements apply. These programs require submission of pricing data and calculation of discounts and rebates pursuant to complex statutory formulas and regulatory guidance, as well as the entry into government procurement contracts governed by the Federal Acquisition Regulations, and the guidance governing such calculations is not always clear. Compliance with such requirements can require significant investment in personnel, systems and resources. Failure to properly calculate prices, or to offer required discounts or rebates could subject us to substantial penalties.

Coverage and Reimbursement

Sales of our approved products and any future products of ours will depend, in part, on the extent to which their costs will be covered by third-party payers, such as government health programs, commercial insurance and managed healthcare organizations. The process for determining whether a third-party payor will provide coverage for a pharmaceutical product is typically separate from the process for setting the price of such a product or for establishing the reimbursement rate that the payor will pay for the product once coverage is approved. Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. As a result, each third-party payer may have its own policy regarding what products it will cover, the conditions under which it will cover such products, and how much it will pay for such products. Third-party payers may limit coverage to specific drug products on an approved list, also known as a formulary, which might not include all of the FDA-approved drugs for a particular indication. Moreover, a third-party payer's decision to provide coverage for a drug product does not guarantee what reimbursement rate, if any, will be approved. Patients may be less likely to use our products if coverage is not provided and reimbursement may not cover a significant portion of the cost of our products. In addition, even if favorable coverage and reimbursement status is attained for one or more products that receives regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

In the U.S. and other potentially significant markets for our products, government authorities and third-party payers are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which may result in lower average selling prices. In some cases, for example, third-party payers try to encourage the use of less expensive generic products through their prescription benefits coverage and reimbursement and co-pay policies. Further, the increased emphasis on managed healthcare in the U.S. and on country-specific and national pricing and reimbursement controls in the EU will put additional pressure on product pricing, reimbursement and usage, which may adversely affect our future product sales and results of operations. These pressures can arise from rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical reimbursement policies and pricing in general. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing coverage and/or reimbursement controls and measures, could have a material adverse impact on our net product revenues and results of operations.

Healthcare Reform

The U.S. and some foreign countries are considering proposals or have enacted legislative and regulatory changes to the healthcare system that could affect our ability to sell our products profitably. Among policy makers and payers in the U.S. and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access.

Over the past decade, there has been increasing legislative and enforcement interest in the U.S. with respect to drug pricing practices. In particular, there have been several recent U.S. Congressional inquiries, hearings and proposed and enacted federal legislation and rules, as well as executive orders and sub-regulatory guidance that may impact pricing for pharmaceutical products. These initiatives include, among others:

- efforts to reevaluate, reduce or limit the prices patients pay for pharmaceutical products;
- implementation of additional data collection and transparency reporting regarding drug pricing, rebates, fees and other remuneration provided by drug manufacturers;

- revisions to rules associated with the calculation of average manufacturer price, best price under Medicaid and rebate liability, in addition to CMS' stated objective to consider additional future rulemaking;
- elimination of the AKS discount safe harbor protection for manufacturer rebate arrangements with Medicare Part D plan sponsors;
- changes to the MDRP, including through a recent CMS-proposed rulemaking for this program, that could significantly increase manufacturer rebate liability; and
- reevaluation of safe harbors under the AKS.

For instance, in August 2022, former President Biden signed the Inflation Reduction Act of 2022 (IRA), which introduced substantial changes to drug pricing, reimbursement and access support in the U.S., including enabling the CMS to assert control over the prices of certain single-source drugs and biotherapeutics reimbursed under Medicare Part B and Part D (the Medicare Drug Price Negotiation Program). The IRA contains a limited exception for small biotech drug manufacturers, which applies on a drug-specific basis, and qualifying drugs will be exempt from possible pricing negotiation through 2028 and eligible for a lower limit (i.e., a price floor) on the potential maximum fair price in 2029 and 2030, if the manufacturers of those drugs continue to qualify each year (small biotech exception). As of the date of this Annual Report on Form 10-K, CMS has informed us that we have qualified for the small biotech exception with respect to our cabozantinib franchise products through 2027. We intend to apply to CMS to maintain the small biotech exception each year through 2030. Separately, in November 2023, CMS released final guidance on another program, the Medicare Part D Manufacturer Discount Program (Part D Discount Program), which will require manufacturers to take on more of the beneficiary cost previously subsidized by the federal government through the application of increased drug discounts. As we received notice from CMS that we qualify for the "specified small manufacturer" designation, we are eligible for a phase-in of the increased manufacturer discounts under the Part D Discount Program, from 2025 to 2031.The manufacturer discount will be 1% in 2025 and will further increase according to a statutory schedule until we are required to pay the full 10% discount (initial phase) in 2029 or the full 20% discount (catastrophic phase) in 2031. The IRA also imposes additional rebates for certain Part B and Part D drugs where relevant pricing metrics associated with the products increase faster than inflation. Over time, the IRA could reduce the revenues we are able to collect from sales of our products or present challenges for payor negotiations and formulary access for our products, as well as increase our government discount and rebate liabilities. However, it is unclear how the IRA will be effectuated or changed under the new Trump Administration and the degree of impact that the IRA will ultimately have upon our business remains unclear.

In addition, the U.S. pharmaceutical industry has also been significantly impacted by other major legislative initiatives and related political contests. For instance, efforts to repeal, substantially modify or invalidate some or all of the provisions of the PPACA, some of which have been successful, have created considerable uncertainties for all businesses involved in healthcare, including our own. Although such attempts to reform the U.S. healthcare system have not significantly impacted our business to date, challenges to the PPACA are ongoing and it is possible that additional legislative, executive and judicial activities in the future could have a material adverse impact on our business, financial condition and results of operations. Further, other legislative changes also have been proposed and adopted since the passage of the PPACA. These have, among other things, reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers.

At the state level, legislatures and regulatory agencies have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biotherapeutic product pricing, including restrictions on pricing or reimbursement at the state government level, limitations on discounts to patients, advance notices of price increases, marketing cost disclosure and transparency measures, and, in some cases, policies to encourage importation from other countries (subject to federal approval) and bulk purchasing. These laws may affect our sales, marketing, and other promotional activities by imposing administrative and compliance burdens on us. In addition, given the lack of clarity with respect to these laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent state and federal authorities.

As a result of these developments and trends, third-party payers are increasingly attempting to contain healthcare costs by limiting coverage and the level of reimbursement of new drugs. These entities could refuse, limit or condition coverage for our products, such as by using tiered reimbursement or pressing for new forms of contracting, or alternatively for patients who rely on our co-pay assistance program, implement co-pay accumulators or maximizers that exempt such co-pay assistance from deductibles (or otherwise modify benefit designs in a manner that takes into account the availability of co-pay assistance), which has increased and could further increase the costs of our co-pay assistance program or cause patients to abandon CABOMETYX or COMETRIQ therapy due to higher out-of-pocket costs. Due to general uncertainty in

the current regulatory and healthcare policy environment, and specifically regarding positions that the Trump Administration may take with respect to these issues, we are unable to predict the impact of any legislative, regulatory, third-party payer or policy actions, including potential cost containment and healthcare reform measures. In addition, it is also possible that CMS could issue new rulemaking or guidance that would affect the amount of rebates owed under the MDRP.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before its cost may be funded within the respective national healthcare system. The requirements governing drug pricing vary widely from country to country. For example, EU Member States may restrict the range of medicinal products for which their national healthcare systems provide reimbursement and may control the prices of medicinal products for human use. A Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profits the medicinal product generates for the company placing it on the market. Pricing and reimbursement negotiations with governmental authorities or payers in EU Member States can take six to 12 months or longer after the initial marketing authorization is granted for a product, or after the marketing authorization for a new indication is granted. To obtain reimbursement and/or pricing approval in some countries, drug manufacturers and collaboration partners may also be required to conduct a study or otherwise provide data that seeks to establish the cost effectiveness of a new drug compared with other available established therapies. Other cost-control initiatives are similarly focused on affordability and accessibility, such as the Regulation on Health Technology Assessment (HTA Regulation) adopted in December 2021 and entering into effect in January 2025, as well as other upcoming legislative and policy changes aimed at increasing cooperation between EU Member States, and once enacted these initiatives may further impact the price and reimbursement status of many medicinal products. There can be no assurance that any country that has price controls, reimbursement limitations or other requirements for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products on cost-effectiveness grounds. Historically, products launched in EU Member States and other non-U.S. jurisdictions do not follow the price structures of the U.S., and they generally tend to be priced significantly lower.

Competition

There are many companies focused on the development of small molecules, antibodies and other treatments for cancer. Our competitors and potential competitors include major pharmaceutical and biotechnology companies, as well as academic research institutions, clinical reference laboratories and government agencies that are pursuing research activities similar to ours. Many of the organizations competing with us have greater capital resources, larger research and development staff and facilities, deeper regulatory expertise and more extensive product manufacturing and commercial capabilities than we do, which may afford them a competitive advantage.

Competition for Cabozantinib

We believe that our ability to compete successfully with cabozantinib in the therapeutic markets where it is or may be approved will depend on, among other things:

- efficacy, safety and reliability of cabozantinib, both alone and in combination with other therapies;
- timing and scope of regulatory approval;
- the speed at which we develop cabozantinib for the treatment of additional tumor types beyond its approved indications;
- our ability to complete clinical development and obtain regulatory approvals for cabozantinib, both alone and in combination with other therapies;
- our ability to manufacture and sell commercial quantities of cabozantinib product to the market;
- our ability to successfully commercialize cabozantinib, both as a single agent and as part of any combination therapy regimen, and secure coverage and adequate reimbursement in approved indications;
- product acceptance by physicians and other health care providers;
- the level of our collaboration partners' investments in the resources necessary to successfully commercialize cabozantinib, or any combination therapy regimen that includes cabozantinib, in territories where they are approved;
- skills of our employees and our ability to recruit and retain skilled employees;
- protection of our intellectual property, including our ability to enforce our intellectual property rights against potential generic competition; and

- the availability of substantial capital resources to fund development and commercialization activities.

We believe that the quality and breadth of activity observed with cabozantinib, the skill of our employees and our ability to recruit and retain skilled employees, our patent portfolio and our capabilities for research and drug development are competitive strengths. However, many large pharmaceutical and biotechnology companies have significantly larger intellectual property estates than we do, substantially more capital resources than we have, and greater capabilities and experience than we do in preclinical and clinical development, sales, marketing, manufacturing and regulatory affairs.

Furthermore, the specific indications for which CABOMETYX is currently or may be approved, based on the results from clinical trials currently evaluating cabozantinib, are highly competitive. Several novel therapies and combinations of therapies have been approved, are in advanced stages of clinical development or are under expedited regulatory review in these indications, and these other therapies are currently competing or are expected to compete with CABOMETYX. While we have had success in adapting our development strategy for the cabozantinib franchise to address the competitive landscape, including through evaluation of therapies that combine ICIs with other targeted agents, it is uncertain whether current and future clinical trials will lead to additional regulatory approvals, or whether physicians will prescribe regimens containing cabozantinib instead of competing product combinations in approved indications.

Below is a summary of the principal competition for cabozantinib in the indications for which it is approved or for which it has been or is currently being evaluated in potentially label-enabling trials, both as a single agent and in combination with other therapies. The information below does not include all competitor products, but rather those approved products that have or we believe may capture significant market share within their respective indications, or with respect to therapies still in development, those that are likely to overlap with patient populations that are or may be treated with cabozantinib or a combination therapy regimen that includes cabozantinib.

Competition in Approved Cabozantinib Indications

CABOMETYX - RCC: We believe the principal competition for CABOMETYX in advanced RCC includes: the combination of Merck & Co.'s pembrolizumab and Pfizer's axitinib; the combination of BMS's ipilimumab and nivolumab; the combination of Merck & Co.'s pembrolizumab and Eisai's lenvatinib; the combination of Eisai's lenvatinib and Novartis' everolimus; and Merck & Co.'s belzutifan. Additionally, there are a variety of therapies being developed for advanced RCC, including: the combination of Merck & Co.'s belzutifan and Eisai's lenvatinib; the combination of Merck & Co.'s pembrolizumab and belzutifan and Eisai's lenvatinib; the combination of Merck & Co.'s pembrolizumab and quavonlimab and Eisai's lenvatinib; and Merck & Co.'s pembrolizumab (administered subcutaneously).

The competitive landscape for RCC is evolving rapidly, especially given the entrance and increased adoption of ICI and ICI-TKI combination therapies into the RCC treatment landscape, particularly in the first-line setting. This has led to changing trends in prescribing and sequencing of certain drugs and combinations across different lines of therapy. It is difficult to predict how these changes will affect sales of CABOMETYX during 2025 and going forward.

CABOMETYX - HCC: We believe the principal competition for CABOMETYX in previously treated HCC includes: Bayer's regorafenib and Eisai's lenvatinib.

The competitive landscape for HCC has changed with the increased adoption of ICI combination therapies in the first-line setting. This has led to increased competition due to the increase in prescribing and sequencing of TKIs in subsequent lines of therapy as more patients overall receive multiple lines of therapy. It is difficult to predict how these changes will affect sales of CABOMETYX during 2025 and going forward.

CABOMETYX - DTC: We believe the principal competition for CABOMETYX in its previously treated DTC indication includes two treatments that are also approved for previously untreated DTC: Bayer's sorafenib and generic versions of sorafenib; and Eisai's lenvatinib. In addition, we believe there is also competition for CABOMETYX from mutation-targeted therapies approved or in development to treat patients with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are RAI-refractory (if RAI is appropriate), or patients with BRAF V600E mutations, including: Blueprint Medicine's and Roche's pralsetinib; Eli Lilly's selpercatinib; and the combination of Novartis' dabrafenib and trametinib.

Other than the approvals of RET inhibitors to treat certain DTC patients, there has been little change in the competitive landscape for RAI-refractory DTC treatments during recent years.

COMETRIQ - MTC: We believe that the principal competing anti-cancer therapy to COMETRIQ in progressive, metastatic MTC is Genzyme's vandetanib, which has been approved by the FDA and the EC for the treatment of symptomatic or progressive MTC in patients with unresectable, locally advanced, or metastatic disease, as well as other therapies that have been recently approved to treat patients with advanced or metastatic RET-mutant MTC who require systemic therapy, including: Blueprint Medicines' and Roche's pralsetinib; and Eli Lilly's selpercatinib.

Other than the recent approvals of RET inhibitors to treat certain MTC patients, there has been little change in the treatment landscape for progressive, metastatic MTC during recent years, and due to the limited number of ongoing late-stage clinical trials in this indication, we do not expect many additional competitors to emerge in 2025.

Competition in Potential Cabozantinib Indications

Cabozantinib in combination with ICI - mCRPC: CONTACT-02 is a phase 3 pivotal trial evaluating the combination of cabozantinib and atezolizumab in patients with measurable extra-pelvic mCRPC who have progressed after treatment with one prior NHT. Should the combination of cabozantinib and atezolizumab be approved for the treatment of these mCRPC patients, we believe its principal competition may include the following approved therapies or therapies in late-stage development: Janssen Biotech's (a wholly owned subsidiary of Johnson & Johnson) abiraterone; Astellas Pharma's and Pfizer's enzalutamide; Sanofi's docetaxel; the combination of Clovis Oncology's rucaparib and Pfizer's enzalutamide; the combination of Clovis Oncology's rucaparib and BMS's nivolumab; the combination of Janssen Biotech's abiraterone and prednisone, with or without Eli Lily's ademaciclib; AstraZeneca PLC's olaparib; and generic versions of abiraterone and docetaxel. In addition, we believe there may be competition for the combination of cabozantinib and atezolizumab in mCRPC from approved therapies or therapies in late-stage development focused on the subset of mCRPC patients who are prostate-specific membrane antigen positive, including: Novartis' lutetium Lu177 vipivotide tetraxetan (formerly 177Lu-PSMA-617); POINT Biopharma's (a wholly owned subsidiary of Eli Lilly) PNT2002 (formerly 177Lu-PNT2002); Telix International's 177Lu-DOTA-rosopatamab; and Curium US LLC's 177Lu-PSMA-I&T.

Cabozantinib - pNET/epNET: CABINET is a phase 3 pivotal trial, which evaluated cabozantinib versus placebo in patients who experienced progression after prior systemic therapy in two independently powered cohorts: pNET and epNET. Should cabozantinib be approved for treatment in patients with pNET and/or epNET, we believe its principal competition may include the following approved therapies or therapies in late-stage development: Novartis' lutetium Lu177 dotatate; Novartis's everolimus; Pfizer's sunitinib; Lantheus Holdings, Inc. and POINT Biopharma's 177Lu-PNT2003; Curium US LLC's 177Lu-DOTATATE; ITM Solucin GmbH's 177Lu-Edotreotide; the combination of Roche's capecitabine and Merck & Co.'s temozolomide; and RayzeBio's Actinium-225 dotatate.

Competition for Zanzalintinib

While we have not yet submitted an NDA to the FDA for zanzalintinib, we believe that the factors that will impact our ability to compete in indications where zanzalintinib may be approved would be similar to those for the cabozantinib franchise, as described above. Below is a summary of the principal competition for zanzalintinib in the indications for which it is currently being evaluated in potentially label-enabling trials, both as a single agent and in combination with other therapies. The information below does not include all competitor products, but rather those approved products that have or we believe may capture significant market share within their respective indications, or with respect to therapies still in development, those that are likely to overlap with patient populations that are or may be treated with zanzalintinib or a combination therapy regimen that includes zanzalintinib.

Competition in Potential Zanzalintinib Indications

Zanzalintinib in combination with ICI - CRC: STELLAR-303 is a phase 3 pivotal trial evaluating the combination of zanzalintinib and atezolizumab in patients with metastatic non-microsatellite instability-high or non-mismatch repair-deficient CRC who have progressed after, or are intolerant to, the current standard of care. Should the combination of zanzalintinib and atezolizumab be approved for the treatment of these CRC patients, we believe its principal competition may include the following approved therapies or therapies in late-stage development: Bayer's regorafenib; Taiho Oncoloy's trifluridine/tipiracil; the combination of Taiho Oncoloy's trifluridine/tipiracil and Roche's bevacizumab; Takeda's fruquintinib; the combination of Agenus' botensilimab and balstilimab; and the combination of Amgen's sotorasib and panitumumab.

Zanzalintinib in combination with ICI - RCC: STELLAR-304 is a phase 3 pivotal trial evaluating zanzalintinib in combination with nivolumab in previously untreated patients with advanced nccRCC. Should the combination of zanzalintinib and nivolumab be approved for the treatment of these RCC patients, we believe its principal competition may

include similar approved therapies or therapies in late-stage development that compete with cabozantinib or combination regimens containing cabozantinib in various RCC indications.

Zanzalintinib in combination with ICI - SCCHN: STELLAR-305 is a phase 2/3 pivotal trial evaluating zanzalintinib in combination with Merck & Co.'s ICI, pembrolizumab, versus pembrolizumab alone in patients with previously untreated PD-L1-positive recurrent or metastatic SCCHN. Should the combination of zanzalintinib and pembrolizumab be approved for the treatment of these SCCHN patients, we believe its principal competition may include the following approved therapies or therapies in late-stage development: the combination of Eli Lily's cetuximab, platinum chemotherapy and 5-fluoruracil; Merck & Co.'s pembrolizumab; and the combination of Merck & Co.'s pembrolizumab, platinum chemotherapy and 5-fluorouracil; the combination of Merus' petosemtamab and Merck & Co's pembrolizumab; and the combination of Bicara's BCA-101 and Merck & Co's pembrolizumab.

Competition for Cobimetinib and Esaxerenone

There is competition for both cobimetinib and esaxerenone in the specific indications and territories where they are approved, and there are regular new entrants and developments in all aspects of these markets. However, given the relatively lesser degree of adoption of these therapies within the broader markets in which they compete and their minimal contribution to our total revenues as out-licensed products, we do not believe changes in the competitive landscape in these indications will have a material impact on our business.

Patents and Proprietary Rights

We actively seek patent protection in the U.S., EU and selected other foreign jurisdictions to cover our product candidates and related technologies. Patents extend for varying periods according to the date of patent filing or grant and the legal term of patents in the various countries where patent protection is obtained. The actual protection afforded by a patent, which can vary from country to country, depends on the type of patent, the scope of its coverage and the availability of legal remedies in the country. We have numerous patents and pending patent applications that relate to compounds and formulations that modulate drug targets, as well as methods of making and using such compounds and formulations.

While many patent applications have been filed relating to the product candidates that we have developed, the majority of these are not yet issued or allowed. To our knowledge, we own all global patents necessary for the continued sale and development of cabozantinib and cobimetinib, and we either own or have in-licensed all global patents for our other product candidates, as further described below.

Cabozantinib

Cabozantinib is covered by more than 15 issued patents in the U.S., building from U.S. Patent No. 7,579,473, for the composition of matter of cabozantinib and pharmaceutical compositions thereof. This composition of matter patent, with patent term extension, will expire in August 2026. The following table describes the U.S. patents that cover our marketed cabozantinib products, and which are listed in the Orange Book. Except as otherwise noted, the stated expiration dates include any patent term adjustments or extensions already granted. In addition to the composition of matter patent referenced above, the table includes patents directed to other aspects of the commercial product. We continue to pursue additional patents and patent term extensions in the U.S. covering various aspects of our cabozantinib products that may, if issued, extend exclusivity beyond the expiration of the patents listed in the table.

Product	Patent No.	General Subject Matter	Patent Expiration
CABOMETYX	7,579,473	Composition of matter	2026
	8,497,284	Methods of treatment	2024
	8,877,776	Salt and polymorphic forms of cabozantinib	2030
	9,724,342	Formulations of cabozantinib	2033
	10,034,873	Methods of treatment	2031
	10,039,757	Methods of treatment	2031
	11,091,439	Crystalline salt forms of cabozantinib	2030
	11,091,440	Pharmaceutical composition	2030
	11,098,015	Methods of treatment	2030
	11,298,349	Pharmaceutical composition essentially free of impurities	2032
	12,128,039	Pharmaceutical composition essentially free of impurities	2032
COMETRIQ	7,579,473	Composition of matter	2026
	8,877,776	Salt and polymorphic forms of cabozantinib	2030
	9,717,720	Formulations of cabozantinib	2032
	11,091,439	Crystalline salt forms of cabozantinib	2030
	11,091,440	Pharmaceutical composition	2030
	11,098,015	Methods of treatment	2030
	11,298,349	Pharmaceutical composition essentially free of impurities	2032
	12,128,039	Pharmaceutical composition essentially free of impurities	2032

Some of our cabozantinib patents have been subject to patent litigation with companies that filed ANDAs seeking to market generic versions of CABOMETYX, as well as others that seek inter partes review (IPR) before the Patent Trial and Appeal Board. We cannot predict the ultimate outcome of these ANDA submissions and/or any related lawsuits and/or IPRs or other challenges that may arise with respect to our patents and patent applications or provide assurance that these lawsuits and/or administrative proceedings will prevent the introduction of a generic version of CABOMETYX for any particular length of time, or at all. For a more detailed discussion of these litigation and administrative matters, see “Note 12. Commitment and Contingencies – Legal Proceedings” of the “Notes to Consolidated Financial Statements” in Part II, Item 8 of this Annual Report on Form 10-K.

In the EU, cabozantinib is protected by issued patents covering the composition of matter until 2029, with Supplementary Protection Certificates. In addition to the composition of matter patent, Exelixis owns certain later-expiring patents directed to the commercial product, including, particular salts, polymorphs, formulations, or use of the compound in the treatment of specified diseases or conditions.

Similarly, in Japan, cabozantinib is protected by issued patents covering the composition of matter, and salts thereof, as well as pharmaceutical compositions and related methods of use. Takeda has applied for patent term extension in Japan to extend the term of the composition of matter patent to 2029. We have other filed patent applications and issued patents in the U.S. and other selected countries covering certain synthetic methods, salts, polymorphs, formulations, prodrugs, metabolites and/or combinations of cabozantinib that, if issued, are anticipated to expire as late as 2037. Outside the U.S. and Japan, cabozantinib is licensed to Ipsen, and in Japan, cabozantinib is licensed to Takeda, each in accordance with the respective collaboration agreements. A discussion of risks and uncertainties that may affect our patent position and other proprietary rights is set forth in “Risk Factors” in Part I, Item 1A of this Annual Report on Form 10-K.

Zanzalintinib and Other Product Candidates

We also have issued patents and pending patent applications, and will continue to file new patent applications, in the U.S., the EU and other selected countries covering zanzalintinib and our other product candidates in clinical and/or preclinical development. Zanzalintinib is covered by U.S. Patent No. 11,542,259, and we have pending patent applications in the U.S. and other selected countries covering the composition of matter, certain synthetic methods, salts, polymorphs,

formulations and combinations of zanzalintinib that, if issued, are anticipated to expire between 2039 and 2044, excluding any potential patent term adjustments and/or extensions.

We have obtained licenses from various parties that give us rights to technologies that we deem to be necessary or desirable for our research and development. These licenses (both exclusive and non-exclusive) may require us to pay royalties as well as upfront and milestone payments.

We require our scientific personnel to maintain laboratory notebooks and other research records in accordance with our policies, which are designed to strengthen and support our intellectual property protection. In addition to our patented intellectual property, we rely on trade secrets and other proprietary information, especially when we do not believe that patent protection is appropriate or can be obtained. We require all of our employees and consultants, outside scientific collaborators, sponsored researchers and other advisors who receive proprietary information from us to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. In addition, these agreements and, in most circumstances, our agreements with consultants, outside scientific collaborators, sponsored researchers and other advisors expressly provide that all inventions, concepts, developments, copyrights, trademarks or other intellectual property developed by an employee during the employment period or developed by a service provider during the service period or utilizing our proprietary drugs or information, shall be our exclusive property. There can be no assurance, however, that these agreements will provide meaningful protection or adequate remedies for our trade secrets in the event of unauthorized use or disclosure of such information.

Human Capital Management

Our Diverse Workforce and Commitment to Inclusion

In January 2024, we announced and implemented a restructuring plan, including a reduction of our employee workforce by approximately 175 employees, or 13% of our then total headcount. As of December 31, 2024, we had 1,147 employees, representing a 12.4% decrease in our employee workforce as compared to December 31, 2023. Of these employees, 558 are members of our research and development teams and 589 are members of our commercial, general and administrative teams. Of these employees, 204 hold Ph.D. degrees, 29 hold M.D. (or foreign equivalent) degrees, 28 hold PharmD degrees and 112 hold other professional degrees such as a J.D. or M.B.A. None of our employees are represented by a labor union, and we consider our employee relations to be good.

During the past five years, our employee turnover has remained consistently below average for the U.S. life sciences industry generally. We continually assess employee turnover, recruitment initiatives, compensation and benefits programs, safety in performing critical laboratory work, diversity and other matters relevant to human capital management, and we review results with our Board of Directors on a periodic basis.

We are an equal opportunity employer and maintain policies that prohibit unlawful discrimination based on race, color, religion, gender, sexual orientation, gender identity/expression, national origin/ancestry, age, disability, marital and veteran status. We are proud to employ a diverse workforce that, as of December 31, 2024, was 57% non-white and 51% women. In addition, as of December 31, 2024, 56% of our positions that manage other employees directly were held by non-whites and 44% were held by women, and women made up 29% of our senior leadership team. We strive to build and nurture a culture where all employees feel empowered to be their authentic selves. We respect and appreciate each employee's unique perspective and experiences, and value their contributions to our mission. It is important that we celebrate, encourage and support similarities and differences to drive innovation for the benefit of our patients, employees and community.

Culture, Compensation and Benefits

At Exelixis, we value being exceptional in what we do and how we lead, excelling for patients by going the extra mile to care for them and exceeding together as a business and contributor to the scientific community. We strive to live these values every day across the company, integrating them into everything from our interview, hiring and onboarding processes, to our performance evaluation, rewards and promotion programs. We provide generous compensation packages designed to attract and retain high-quality employees, and all of our employees are eligible for cash bonuses and grants of long-term incentive awards. We regularly evaluate our compensation programs with an independent compensation consultant and utilize industry benchmarking to ensure our programs are competitive with the biotechnology and biopharmaceutical companies against which we compete for talent. We also work with third party consultants to conduct an annual, independent pay equity analysis to ensure our compensation programs are fair and equitable across our workforce with respect to gender, race and other personal characteristics. We are proud to provide a variety of programs

and services to help employees meet and balance their needs at work, at home and in life, including an attractive mix of healthcare, insurance and other benefit plans. We deliver a benefits program that is designed to keep our employees and their families mentally, physically and emotionally healthy, which includes not only medical, dental and vision benefits, but also a wellness subsidy program, virtual and onsite fitness classes, adoption assistance, mental health coverage, subsidized commuter benefits and other wellness benefits. Our inclusive benefits are also designed to support family life with options including, among others, generous parental leave policies, grandparent leave, adoption, surrogacy and fertility programs, new parent and nursing mother support programs, mental health services, childcare tuition subsidy and tutoring services, dependent care for children and adults, family care coordination, and pet insurance. For a discussion of workplace safety measures we have taken, see "—Environmental, Health and Safety."

Beyond compensation and benefits, we also value career development for all employees, and we offer a tuition reimbursement program, as well as professional development courses ranging from technical training, competency-based workshops and leadership development programs facilitated by external partners who are experts in their respective fields. In 2024, we established the Exelixis Leadership Foundations, a comprehensive two-year leadership program designed exclusively to assist managers in achieving outcomes effectively. Managers also take an active role in identifying individualized development plans to assist their employees in realizing their full potential and creating opportunities for promotions and added responsibilities that enhance the engagement and retention of our workforce.

Corporate Information

We were incorporated in Delaware in November 1994 as Exelixis Pharmaceuticals, Inc. and changed our name to Exelixis, Inc. in February 2000. Our principal executive offices are located at 1851 Harbor Bay Parkway, Alameda, California 94502. Our telephone number is (650) 837-7000. We maintain a site on the worldwide web at www.exelixis.com; however, information found on our website is not incorporated by reference into this report.

We make available free of charge on or through our website our Securities and Exchange Commission (SEC) filings, including our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. The SEC maintains a site on the worldwide web that contains reports, proxy and information statements and other information regarding our filings at www.sec.gov.

Item 1A. Risk Factors.

In addition to the risks discussed elsewhere in this report, the following are important factors that make an investment in our securities speculative or risky, and that could cause actual results or events to differ materially from those contained in any forward-looking statements made by us or on our behalf. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not currently known to us or that we deem immaterial also may impair our business operations. If any of the following risks or such other risks actually occur, our business and the value of your investment in our company could be harmed.

Risks Related to the Commercialization of Our Products

Our ability to grow our company is dependent upon the commercial success of CABOMETYX in its approved indications and the continued clinical development, regulatory approval, clinical acceptance and commercial success of the cabozantinib franchise in additional indications.

We anticipate that for the foreseeable future, our ability to maintain or meaningfully increase cash flow to fund our business operations and growth will depend upon the continued commercial success of CABOMETYX, both alone and in combination with other therapies, as a treatment for the highly competitive indications for which it is approved, and possibly for other indications for which cabozantinib is currently being evaluated in potentially label-enabling clinical trials, if warranted by the data generated from these trials. In this regard, part of our strategy is to pursue additional indications for CABOMETYX and increase the number of cancer patients who could potentially benefit from this medicine. However, we cannot be certain that the clinical trials we and our collaboration partners are conducting will demonstrate adequate safety and efficacy in these additional indications to receive regulatory approval in the major commercial markets where CABOMETYX is approved. Even if the required regulatory approvals to market CABOMETYX for additional indications are achieved, we and our collaboration partners may not be able to commercialize CABOMETYX effectively and successfully in these additional indications. If revenue from CABOMETYX decreases or remains flat, or if we are unable to expand the

number of labeled indications for which CABOMETYX is approved, or if we or our collaboration partners fail to achieve anticipated product royalties and collaboration milestones, we may need to reduce our operating expenses, access other sources of cash or otherwise modify our business plans, which could have a material adverse impact on our business, financial condition and results of operations.

Our ability to grow revenues from sales of CABOMETYX depends upon the degree of market acceptance among physicians, patients, healthcare payers, and the medical community.

Our ability to increase or maintain revenues from sales of CABOMETYX for its approved indications is, and if approved for additional indications will be, highly dependent upon the extent of market acceptance of CABOMETYX among physicians, patients, foreign and U.S. government healthcare payers such as Medicare and Medicaid, commercial healthcare plans and the medical community. Market acceptance for CABOMETYX could be impacted by numerous factors, including the effectiveness and safety profile, or the perceived effectiveness and safety profile, of CABOMETYX compared to competing products, the strength of CABOMETYX sales and marketing efforts and changes in pricing and reimbursement for CABOMETYX. If CABOMETYX does not continue to be prescribed broadly for the treatment of patients in its approved indications, our product revenues could flatten or decrease, which could have a material adverse impact on our business, financial condition and results of operations.

Our competitors may develop products and technologies that impair the relative value of our marketed products and any current and future product candidates.

The biopharmaceutical industry is competitive and characterized by constant technological change and diverse offerings of products, particularly in the area of oncology therapies. Many of our competitors have greater capital resources, larger research and development staff and facilities, deeper organizational regulatory experience and more extensive product manufacturing and commercial capabilities than we do, which may afford them a competitive advantage. Further, our competitors may be more effective at in-licensing and developing new commercial products that could render our products, and those of our collaboration partners, obsolete or noncompetitive. We face, and will continue to face, intense competition from biopharmaceutical companies, as well as academic research institutions, clinical reference laboratories and government agencies that are pursuing scientific and clinical research activities similar to ours.

Furthermore, the specific indications for which CABOMETYX is currently or may be approved, based on the results from clinical trials currently evaluating cabozantinib, are highly competitive. Several novel therapies and combinations of therapies have been approved, are in advanced stages of clinical development or are under expedited regulatory review in these indications, and these other therapies are currently competing or are expected to compete with CABOMETYX, or the FDA may update their labeling to add accepted indications that compete with CABOMETYX. Even if our current and future clinical trials produce positive results sufficient to obtain marketing approval by the FDA and other global regulatory authorities, it is uncertain whether physicians will choose to prescribe regimens containing our products instead of competing products and product combinations in approved indications.

If we are unable to maintain or increase our sales, marketing, market access and product distribution capabilities for our products, we may be unable to maximize product revenues, which could have a material adverse impact on our business, financial condition and results of operations.

Maintaining our sales, marketing, market access and product distribution capabilities requires significant resources, and there are numerous risks involved with maintaining and continuously improving our commercial organization, including our potential inability to successfully recruit, train, retain and incentivize adequate numbers of qualified and effective sales and marketing personnel. We are competing for talent with numerous commercial- and precommercial-stage, oncology-focused biopharmaceutical companies seeking to build out and maintain their commercial organizations, as well as larger biopharmaceutical organizations that have extensive, well-funded and more experienced sales and marketing operations, and we may be unable to maintain or adequately scale our commercial organization as a result of such competition. Also, to the extent that the commercial opportunities for CABOMETYX grow over time, we may not properly scale the size and experience of our commercialization teams to market and sell CABOMETYX successfully in an expanded number of indications. If we are unable to maintain or scale our commercial function appropriately, we may not be able to maximize product revenues, which could have a material adverse impact on our business, financial condition and results of operations.

If we are unable to obtain or maintain coverage and reimbursement for our products from government and other third-party payers, our business will suffer.

Our ability to commercialize our products successfully is highly dependent on the extent to which health insurance coverage and reimbursement is, and will be, available from third-party payers, including foreign and U.S. governmental payers, such as Medicare and Medicaid, and private health insurers. Third-party payers continue to scrutinize and manage access to pharmaceutical products and services and may limit reimbursement for newly approved products and indications. Patients are generally not capable of paying for CABOMETYX or COMETRIQ themselves and rely on third-party payers to pay for, or subsidize, the costs of their medications, among other medical costs. Accordingly, market acceptance of CABOMETYX and COMETRIQ is dependent on the extent to which coverage and reimbursement is available from third-party payers. These payer entities could refuse, limit or condition coverage for our products, such as by using tiered reimbursement or pressing for new forms of contracting, or alternatively for patients who rely on our co-pay assistance program, implementing co-pay accumulators or maximizers that exempt such co-pay assistance from patient deductibles (or otherwise modify benefit designs in a manner that takes into account the availability of co-pay assistance), which actions have increased and could further increase the costs of our co-pay assistance program or cause patients to abandon CABOMETYX or COMETRIQ therapy due to higher out-of-pocket costs. In April 2024, the CMS finalized regulations that will mitigate maximizer programs by requiring individual and small group market health plans to consider as essential health benefits (EHB) all prescription drugs that are covered in excess of a state's EHB benchmark plan. The Departments of Labor, Treasury, and Health and Human Services stated their intent to address the application of this policy to large group market and self-insured plans in future rulemaking. CMS also plans to address in future rulemaking the application of manufacturer assistance to the annual cost-sharing limit; this follows a 2023 federal district court decision vacating a rule that provided health plans with discretion whether to include manufacturer assistance toward the annual cost-sharing limit. If third-party payers do not provide or increase limitations on coverage or reimbursement for CABOMETYX or COMETRIQ, our revenues and results of operations may suffer. In addition, even if third-party payers provide some coverage or reimbursement for CABOMETYX or COMETRIQ, the availability of such coverage or reimbursement for prescription drugs under private health insurance and managed care plans, which often varies based on the type of contract or plan purchased, may not be sufficient for patients to afford CABOMETYX or COMETRIQ.

Current healthcare laws and regulations in the U.S. and future legislative or regulatory reforms to the U.S. healthcare system may affect our ability to commercialize our marketed products profitably.

Concern over access to and affordability of pharmaceutical products continues to spur debate and action by U.S. federal and state government authorities in an effort to contain costs. Such legislative and regulatory proposals include price transparency reporting obligations, use of mandated discounts and restrictive formularies, among others. If implemented, the resulting changes to the pricing and reimbursement of CABOMETYX and COMETRIQ could affect our ability to continue to commercialize the products. Consolidation and integration of private payers and pharmacy benefit managers in the U.S. has also significantly impacted the market for pharmaceuticals by increasing payer leverage in negotiating manufacturer price or rebate concessions and pharmacy reimbursement rates. Such restrictive or unfavorable pricing, coverage or reimbursement determinations for CABOMETYX and COMETRIQ or our other product candidates, whether made by governments (including regulatory agencies and courts) or by private payers, may adversely impact our business.

In addition, there have been, and may in the future be, initiatives at both the federal and state level or legal challenges that could significantly modify the terms and scope of government-provided health insurance coverage, ranging from changes to or litigation opposing some or all of the provisions of the PPACA, to establishing a single-payer, national health insurance system, to more limited "buy-in" options to existing public health insurance programs, any of which could have a significant impact on the healthcare industry. Although such attempts to reform the U.S. healthcare system have not significantly impacted our business to date, it is possible that additional legislative, executive and judicial activities in the future could have a material adverse impact on our business, financial condition and results of operations.

Furthermore, because we participate in the 340B Program to sell a portion of our marketed products, changes in the administration of the program could have a material adverse impact on our revenues. Effective July 2022, we implemented a 340B Program Integrity Initiative, pursuant to which we request all hospital covered entities (i.e., hospitals that participate in the 340B Program) to provide claims-level data for CABOMETYX and COMETRIQ dispensed by contract pharmacies. A covered entity that elects not to provide this limited claims data and that does not have an in-house pharmacy may designate a single contract pharmacy location within our authorized specialty pharmacy network. We believe this initiative will provide much-needed transparency and promote compliance with program requirements, and at the same time, should not restrict patient access to our medicines.

In 2021, other manufacturers that implemented similar contract pharmacy integrity programs received enforcement letters from the U.S. Department of Health and Human Services (HHS) stating that those manufacturers' integrity initiatives, as implemented, restricted contract pharmacy transactions in violation of the 340B Program statute. Certain of these other manufacturers engaged in litigation with the government over the legality of these programs. In November 2023, we received from several covered entities a 340B Program Administrative Dispute Resolution (ADR) petition, seeking to invoke an administrative adjudication process overseen by the HHS' Health Resources and Services Administration (HRSA). The petitioners contend that the Company's 340B Program Integrity Initiative caused them to be overcharged for CABOMETYX and COMETRIQ. We have since received confirmation that the HRSA will assign an ADR panel to the claim, and responded to the complaint in October 2024. At this time it is unclear what, if any, liabilities we might incur as a party to this ADR proceeding.

In addition, certain states have also enacted laws requiring manufacturers to provide the 340B Program pricing through contract pharmacy arrangements; these laws are also being challenged in ongoing litigation. We believe our 340B Program Integrity Initiative complies with the 340B Program statute, as supported by the federal appellate court decision in *Sanofi Aventis U.S. LLC v. United States Department of Health and Human Services* and *Novartis v. Johnson*, and that the state laws regarding contract pharmacy arrangements are invalid or are otherwise inapplicable to our 340B Program Integrity Initiative. With particular respect to AR Act 1103 (the Arkansas law concerning the 340B Program contract pharmacy arrangements), following the federal appellate court ruling in *Pharmaceutical Research and Manufacturers of America v. McClain*, we are voluntarily complying with AR Act 1103 and certain other state laws.

Depending on the outcome of the ongoing litigation or any specific proceedings involving us, we may be required to modify or suspend our 340B Program Integrity Initiative. Ultimately, any negative ruling in a federal court, HHS administrative proceeding, or state-level proceeding in which we are a party, or in which the compliance of our 340B Program Integrity Initiative is at issue, could have a material adverse effect on our business, financial condition and results of operations. Due to general uncertainty with respect to this litigation and in the current regulatory and healthcare policy environment, and specifically regarding positions that the Trump Administration may take with respect to these issues, we are unable to predict the impact of any future legislative, regulatory, third-party payer or policy actions, including potential cost containment and healthcare reform measures. If enacted, we and any third parties we might engage may be unable to adapt to any changes implemented as a result of such measures, and we could face difficulties in maintaining or increasing profitability or otherwise experience a material adverse impact on our business, financial condition and results of operations.

Pricing for pharmaceutical products in the U.S. has come under increasing attention and scrutiny by federal and state governments, legislative bodies and enforcement agencies. Initiatives arising from this scrutiny may result in changes that have the effect of reducing our revenue or harming our business or reputation.

There continue to be U.S. Congressional inquiries, hearings and proposed and enacted federal legislation and rules, as well as executive orders and sub-regulatory guidance, that may impact pricing for pharmaceutical products. These initiatives include, among others:

- efforts to reevaluate, reduce or limit the price patients pay for pharmaceutical products;
- implementation of additional data collection and transparency reporting regarding drug pricing, rebates, fees and other remuneration provided by drug manufacturers;
- revisions to rules associated with the calculation of average manufacturer price; best price and rebate liability (including broadening the circumstances under which products are subject to rebate) for the MDRP, along with CMS' stated objective to consider potential future rulemaking that if implemented, could significantly increase manufacturer rebate liability; and
- reevaluation of safe harbors under the AKS.

For instance, in August 2022, former President Biden signed the IRA, which among other things: enables CMS to assert control over the prices of certain single-source drugs and biotherapeutics reimbursed under the Medicare Drug Price Negotiation Program; subjects drug manufacturers to potential civil monetary penalties and a significant excise tax for offering a price that is not equal to or less than the government-imposed "maximum fair price" under the law; imposes Medicare rebates for certain Part B and Part D drugs where relevant pricing metrics associated with the products increase faster than inflation; and redesigns the funding and benefit structure of the Medicare Part D program, potentially increasing manufacturer liability while capping annual out-of-pocket drug expenses for Medicare beneficiaries. These provisions started taking effect incrementally in late 2022 and currently are subject to various legal challenges. As of the date of this report, for example, CMS has begun to implement aspects of the IRA and finalized regulations addressing the Medicare Part

B and Medicare Part D inflation rebate provisions of the IRA. These provisions generally require manufacturers of Medicare Part B and Part D rebatable drugs to pay inflation rebates to the Medicare program if pricing metrics associated with their products increase faster than the rate of inflation. In addition, in October 2024, CMS released final guidance setting forth the requirements and procedures for implementing the Medicare Drug Price Negotiation Program for the second round of drug pricing evaluations (which commences in 2025 and will result in maximum fair prices that will become effective beginning in 2027), as well as requirements for manufacturers in effectuating maximum fair prices in 2026 and 2027. The IRA also contains the limited small biotech exception, which applies on a drug-specific basis. Qualifying drugs may be exempt from possible pricing negotiation through 2028 and eligible for a lower limit (i.e., a price floor) on the potential maximum fair price in 2029 and 2030, if the manufacturers of those drugs continue to qualify each year. We have qualified for the small biotech exception with respect to our cabozantinib franchise products through 2027. We intend to apply to CMS to maintain the small biotech exception through 2030. In January 2025, CMS announced the list of 15 drugs selected for the second round of drug pricing evaluations. Separately, in November 2023, CMS released final guidance on the Part D Discount Program, which will require manufacturers to take on more of the beneficiary cost previously subsidized by the federal government through the application of increased drug discounts. As we received notice from CMS that we qualify for the "specified small manufacturer" designation, we are eligible for a phase-in of the increased manufacturer discounts under the Part D Discount Program from 2025 to 2031. Beginning in 2025, we will be required to pay a 1% discount in the initial and catastrophic phases, and provided that we maintain the specified small manufacturer designation, we will be required to increase our rebates to Part D payers until we are required to pay the full 10% discount (initial phase) in 2029 and the 20% discount (catastrophic phase) in 2031. CMS is also in the process of implementing the Medicare Prescription Payment Plan, under which Medicare Part D beneficiaries may opt to make their cost-sharing payments in capped monthly installments; CMS expects that this program will most likely benefit those beneficiaries with high cost-sharing early in their respective plan years.

Over time, the IRA could reduce the revenues we are able to collect from sales of our products or present challenges for payer negotiations and formulary access for our products, as well as increase our government discount and rebate liabilities; however, the degree of impact that the IRA will ultimately have upon our business remains unclear. In addition, we cannot know the final form or timing of any other legislative, regulatory and/or administrative measures, and some of these pending and enacted policy changes, if implemented as currently proposed, would likely have significant and far-reaching impacts on the biopharmaceutical industry and therefore likely also have a material adverse impact on our business, financial condition and results of operations. Additionally, there is ongoing litigation challenging the Medicare Drug Price Negotiation Program, and we cannot predict the outcome of these cases.

At the state level, legislatures and regulatory agencies have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biotherapeutic product pricing, including restrictions on pricing or reimbursement at the state government level, limitations on discounts to patients, advance notices of price increases, marketing cost disclosure and transparency measures, and, in some cases, policies to encourage importation from other countries (subject to federal approval) and bulk purchasing. Furthermore, adoption of these drug pricing transparency regulations, and our associated compliance obligations, may increase our general and administrative costs and/or diminish our revenues. Implementation of these federal and/or state cost-containment measures or other healthcare reforms may limit our ability to generate product revenue or commercialize our products, and in the case of drug pricing transparency regulations, may result in fluctuations in our results of operations.

Lengthy regulatory pricing and reimbursement procedures and cost control initiatives imposed by governments outside the U.S. could delay the marketing of and/or result in downward pressure on the price of our approved products, resulting in a decrease in revenue.

Outside the U.S., including major markets in the EU and Japan, the pricing and reimbursement of prescription pharmaceuticals is generally subject to significant governmental control. In these countries, pricing and reimbursement negotiations with governmental authorities or payers can take six to 12 months or longer after the initial marketing authorization is granted for a product, or after the marketing authorization for a new indication is granted. This can substantially delay broad availability of the product. To obtain reimbursement and/or pricing approval in some countries, our collaboration partners Ipsen and Takeda may also be required to conduct a study or otherwise provide data that seeks to establish the cost effectiveness of CABOMETYX compared with other available established therapies. The conduct of such a study could also result in delays in the commercialization of CABOMETYX.

Additionally, cost-control initiatives, increasingly based on affordability and accessibility, as well as post-marketing assessments of the added value of CABOMETYX and COMETRIQ as compared to existing treatments, could influence the prices paid for and net revenues we realize from CABOMETYX and COMETRIQ, or the indications for which we are able to

obtain reimbursement, which would result in lower license revenues to us. Recent legislative changes and ongoing policy changes in the EU are aimed at increasing cooperation between the EU Member States. Such initiatives, particularly the Regulation on Health Technology Assessment adopted in December 2021 and entered into application in January 2025, may further impact the price and reimbursement status of CABOMETYX and COMETRIQ.

The timing of the entrance of generic competitors to CABOMETYX and legislative and regulatory action designed to reduce barriers to the development, approval and adoption of generic drugs in the U.S. could limit the revenue we derive from our products, most notably CABOMETYX, which could have a material adverse impact on our business, financial condition and results of operations.

Under the FDCA, the FDA can approve an ANDA for a generic version of a branded drug without the applicant undertaking the human clinical testing necessary to obtain approval to market a new drug. The FDA can also approve a 505(b)(2) NDA that relies in part on the agency's findings of safety and/or effectiveness for a previously approved drug, where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use. Both the ANDA and 505(b)(2) NDA processes are discussed in more detail in "Item 1. Business—Government Regulation—FDA Review and Approval—Abbreviated FDA Approval Pathways and Generic Products" of this Annual Report on Form 10-K. In either case, if an ANDA or 505(b)(2) NDA applicant submits an application referencing one of our marketed products prior to the expiry of one or more of our Orange Book-listed patents for the applicable product and includes a paragraph IV certification asserting that the patents are invalid or not infringed, we may litigate with the potential generic competitor to protect our patent rights, which would result in substantial costs, divert the attention of management, and could have an adverse impact on our stock price. For example, MSN and Sun have separately submitted ANDAs to the FDA requesting approval to market their respective generic versions of CABOMETYX tablets, and we have subsequently filed patent infringement lawsuits against these companies. For a more detailed discussion of these litigation matters, see "Legal Proceedings" in Part I, Item 3 of this Annual Report on Form 10-K. It is possible that MSN or Sun or other companies, following FDA approval of an ANDA or 505(b)(2) NDA, could introduce generic or otherwise competitor versions of our marketed products before our patents expire if they do not infringe our patents or if it is determined that our patents are invalid or unenforceable, and we expect that generic cabozantinib products would be offered at a significantly lower price compared to our marketed cabozantinib products. Regardless of the regulatory approach, the introduction of a generic version of cabozantinib would likely decrease our revenues derived from the U.S. sales of CABOMETYX and thereby materially harm our business, financial condition and results of operations. There are also equivalent procedures in the EU permitting authorization of generic versions of medicinal products authorized in the EU once related data and market exclusivity periods have expired.

The U.S. federal government has also taken numerous legislative and regulatory actions to expedite the development and approval of generic drugs. Both Congress and the FDA are considering, and have enacted, various legislative and regulatory proposals focused on drug competition, including legislation focused on drug patenting and provision of drug to generic applicants for testing. For example, the Ensuring Innovation Act, enacted in April 2021, amended the FDA's statutory authority for granting NCE exclusivity to reflect the agency's existing regulations and longstanding interpretation that award NCE exclusivity based on a drug's active moiety, as opposed to its active ingredient, which is intended to limit the applicability of NCE exclusivity, thereby potentially facilitating generic competition. In addition, the Further Consolidated Appropriations Act, 2020, which incorporated the framework from the Creating and Restoring Equal Access To Equivalent Samples (CREATES) legislation, allows ANDA, 505(b)(2) NDA or biosimilar developers to obtain access to quantities of branded drug and biological product samples necessary to conduct research and development. Further, Section 3222 of the 2023 Appropriations Act requires the FDA to make therapeutic equivalence determinations for 505(b)(2) NDAs at the time of approval, or up to 180 days thereafter, if requested by the applicant. Additionally, Section 3224 of the 2023 Appropriations Act allows the FDA to approve an ANDA even if there are differences between the generic drug's proposed labeling and that of the listed drug due to the FDA approving a change to the listed drug's label (excluding warnings) within 90 days of when the ANDA is otherwise eligible for approval, provided that the ANDA applicant agrees to submit revised labeling for the generic drug within 60 days of approval. In addition, the policies introduced in the Generic Drug User Fee Amendments Commitment Letter give the FDA greater flexibility to approve ANDAs without adding additional review cycles when there are changes to the reference listed drug that may previously have delayed approval. While the full impact of these provisions is unclear at this time, they have the potential to facilitate the development and future approval and market success of generic versions of our products, introducing generic competition that could have a material adverse impact on our business, financial condition and results of operations. Moreover, in September 2023, the FTC issued a policy statement, supported by the FDA, warning brand pharmaceutical companies that they could face legal action under the FTC Act if they improperly list patents in the Orange Book, and it subsequently initiated challenges against patents held by brand pharmaceutical companies and listed in the Orange Book

under the FDA's patent listing dispute process. In December 2024, the Federal Circuit ruled that, to be listed in the Orange Book, a patent must claim the active ingredient of the drug product. If affirmed on appeal, this decision may limit the number of patents brand pharmaceutical companies may list in the Orange Book.

Risks Related to Growth of Our Product Portfolio and Research and Development

We may be unable to expand our discovery and development pipeline, which could limit our growth and revenue potential.

Our business is focused on the discovery, development and commercialization of new medicines for difficult-to-treat cancers. In this regard, we have invested substantial technical, financial and human resources toward drug discovery activities with the goal of identifying new potential product candidates to advance into clinical trials. Notwithstanding this investment, many drug discovery programs that initially show promise will ultimately fail to yield clinical product candidates for multiple reasons. For example, product candidates and preclinical development candidates may, on further study, be shown to have inadequate efficacy, harmful side effects, suboptimal pharmaceutical profiles or other characteristics suggesting that they are unlikely to become commercially viable products.

Apart from our drug discovery efforts, our strategy to expand our development pipeline is also dependent on our ability to successfully identify and acquire or in-license relevant investigational oncology assets and technologies. However, the in-licensing and acquisition of investigational oncology assets and technologies is a highly competitive area, and many other companies are pursuing the same or similar investigational oncology assets and technologies to those that we may consider attractive. In particular, larger companies with more capital resources and more extensive clinical development and commercialization capabilities may have a competitive advantage over us. Furthermore, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We may also be unable to in-license or acquire additional investigational oncology assets and technologies on acceptable terms that would allow us to realize an appropriate return on our investment. Even if we succeed in our efforts to obtain rights to suitable investigational oncology assets and technologies, the competitive business environment may result in higher acquisition or licensing costs, and our investment in these potential product candidates and technologies will remain subject to the inherent risks associated with the development and commercialization of new medicines. In certain circumstances, we may also be reliant on licensors for the continued development of any product candidates and/or technologies that we have in-licensed and such licensors' efforts to safeguard their underlying intellectual property.

With respect to acquisitions, we may not be able to integrate the target company successfully into our existing business, maintain the key business relationships of the target company, or retain key personnel of the acquired business. Furthermore, we could assume unknown or contingent liabilities or otherwise incur unanticipated expenses. Any acquisitions or investments made by us also could result in our spending significant amounts of resources, issuing dilutive securities, assuming or incurring significant debt obligations and contingent liabilities, incurring large one-time expenses, and acquiring intangible assets that could result in significant future amortization expense and significant write-offs, any of which could harm our financial condition and results of operations. If our drug discovery efforts, including research collaborations, in-licensing arrangements and other business development activities, do not result in suitable product candidates, our business and prospects for growth could suffer.

Clinical testing of cabozantinib for new indications, or of our other product candidates, such as zanzalintinib, is a lengthy, costly, complex and uncertain process that may ultimately fail to demonstrate sufficiently differentiated safety and efficacy data for those products to compete in our highly competitive market environment.

Clinical trials are inherently risky and may reveal that cabozantinib, despite its approval for certain indications, or a new product candidate, such as zanzalintinib, is ineffective or has an unacceptable safety profile with respect to an intended use. Such results may significantly decrease the likelihood of regulatory approval of a product candidate or of an approved product for a new indication. Moreover, the results of preliminary studies do not necessarily predict clinical or commercial success, and late-stage or other potentially label-enabling clinical trials may fail to confirm the results observed in early-stage trials or preliminary studies. Although we have established timelines for manufacturing and clinical development of cabozantinib, zanzalintinib and our other product candidates based on existing knowledge of our compounds in development and industry metrics, we may not be able to meet those timelines.

We may experience numerous unforeseen events, during or as a result of clinical investigations, that could delay or prevent commercialization of cabozantinib in new indications or of zanzalintinib or our other new product candidates. These events may include:

- lack of acceptable efficacy or a tolerable safety profile;
- being placed on clinical hold by the FDA due to safety or effectiveness concerns;
- negative or inconclusive clinical trial results that require us to conduct further testing or to abandon projects;
- discovery or commercialization by our competitors of other compounds or therapies that demonstrate potentially superior safety or efficacy profiles as compared to cabozantinib, zanzalintinib or our other product candidates;
- our inability to identify and maintain a sufficient number of clinical trial sites;
- lower-than-anticipated patient registration or enrollment in our clinical testing;
- additional complexities posed by clinical trials evaluating cabozantinib, zanzalintinib or our other product candidates in combination with other therapies, including extended timelines to provide for collaboration on clinical development planning, the failure by our collaboration partners to provide us with an adequate and timely supply of product that complies with the applicable quality and regulatory requirements for a combination trial;
- reduced staffing or shortages in laboratory supplies and other resources necessary to complete the trials;
- replacement of staff at the FDA's OCE that changes OCE's view of the acceptability of the design, conduct, or data produced by our clinical trials;
- failure of our third-party contract research organizations or investigators to satisfy their contractual obligations, including deviating from any trial protocols or failing to adhere to appropriate recordkeeping or data integrity requirements; and
- withholding of authorization from regulators or institutional review boards to commence or conduct clinical trials or delays, variations, suspensions or terminations of clinical research for various reasons, including noncompliance with regulatory requirements or a determination by these regulators and institutional review boards that participating patients are being exposed to unacceptable health risks.

Further, with the passage of the Food and Drug Omnibus Reform Act of 2022 (FDORA), Congress clarified the FDA's authority to conduct inspections by expressly permitting inspection of facilities involved in the preparation, conduct or analysis of clinical and non-clinical studies submitted to the FDA, as well as of other persons holding study records or otherwise involved in the study process, which could delay or add complexity to our clinical trials.

The ongoing Russia-Ukraine and Israel-Hamas conflicts have had modest impacts on our clinical development operations and may continue to have adverse impacts on the ability of clinical sites and enrolled patients to adhere to trial protocols for in-office clinical visits and other procedures, our ability to supply clinical sites with cabozantinib, zanzalintinib or other study drugs and to pay clinical sites and investigators for work performed, as well as our ability to collect data and conduct site monitoring visits, all of which could undermine the data quality for patients enrolled at these clinical sites. These issues could further impact our anticipated timelines for completing the trials and achieving clinical endpoints, as well as increase our clinical development expenses. If there are further delays in or termination of the clinical testing of cabozantinib, zanzalintinib or our other product candidates due to any of the events described above or otherwise, our expenses could increase and our ability to generate revenues could be impaired, either of which could adversely impact our financial results. Furthermore, we have relied and may in the future rely on collaboration partners to share a significant portion of the expenses associated with our clinical development programs. Should one or all of our collaboration partners decline to support future planned clinical trials, we will be entirely responsible for financing the further development of the cabozantinib franchise, zanzalintinib or our other product candidates and, as a result, the burden of clinical trial expenses we incur associated with our business plans may be materially greater than currently anticipated, which could have a material adverse impact on our business, financial condition and results of operations.

We may not be able to pursue the further development of the cabozantinib franchise, zanzalintinib or our other product candidates or meet current or future requirements of the FDA or regulatory authorities in other jurisdictions in accordance with our stated timelines or at all. Our planned clinical trials may not begin on time, or at all, may not be completed on schedule, or at all, may not be sufficient for registration of our product candidates or otherwise may not result in an approvable product. The duration and the cost of clinical trials vary significantly due to a number of factors, including, but not limited to: the characteristics of the product candidate under investigation; the number of patients who ultimately participate in the clinical trial; the duration of patient follow-up; the number of clinical sites included in the trial;

and the length of time required to enroll eligible patients. Any delay could limit our ability to generate revenues, cause us to incur additional expenses and cause the market price of our common stock to decline significantly.

The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, uncertain and subject to change, and may not result in regulatory approvals for additional cabozantinib indications or for our other product candidates, such as zanzalintinib, which could have a material adverse impact on our business, financial condition and results of operations.

The activities associated with the research, development and commercialization of the cabozantinib franchise, zanzalintinib and our other product candidates are subject to extensive regulation by the FDA and other regulatory agencies in the U.S., as well as by comparable regulatory authorities in other territories. The processes of obtaining regulatory approvals in the U.S. and other foreign jurisdictions are expensive and often takes many years, if approval is obtained at all, and they can vary substantially based upon the type, complexity and novelty of the product candidates involved. For example, before an NDA or sNDA can be submitted to the FDA, or a MAA to the EMA or any application or submission to comparable regulatory authorities in other jurisdictions, the product candidate must undergo extensive clinical trials, which can take many years and require substantial expenditures.

Any clinical trial may fail to produce results satisfactory to the FDA or regulatory authorities in other jurisdictions. The FDA has substantial discretion in the approval process and may refuse to approve any NDA or sNDA or require additional preclinical, clinical, safety or other non-clinical studies. In addition, policy-based activities could delay the approval of an application for cabozantinib, zanzalintinib, or our other product candidates. For example, the FDA's OCE has many initiatives aimed at improving oncology drug development, some of which may lead to the need for additional studies, such as dose optimization. Many of these initiatives are based on guidance issued by OCE. If the FDA chooses to withdraw those guidance documents for any reason it may affect our ability to gain regulatory approval based on studies that relied on those guidance documents. The FDA also continues to develop and finalize guidance documents that further refine the development process for oncology drug products. And, as this market expands, it becomes increasingly difficult to demonstrate benefit over the standard of care, which can be a hurdle for approval. Moreover, the development of our product candidates may be delayed by other events beyond our control. For example, action by the new Trump Administration to limit federal agency budgets or personnel, may result in reductions to the FDA's budget, employees, and operations, which may lead to slower response times and longer review periods, potentially affecting our ability to progress development of our product candidates or obtain regulatory approval for our product candidates.

The FDA has also been tightening the requirements for confirmatory studies for drugs approved via accelerated approval under additional authorities the Agency received in Section 3210 of the FDORA (incorporated in the 2023 Appropriations Act). While the standard for accelerated approval remains unchanged, the FDA may now require that confirmatory trials for drugs approved under the pathway be underway prior to approval, which was not previously a requirement. The changes to the law are intended to prevent accelerated approval of drugs without verified clinical benefit, which had previously resulted in withdrawal of approval for certain products and indications approved on an accelerated basis. While it is not clear at this time how these legislative and regulatory initiatives will affect our plans to pursue accelerated approval for one or more of our product candidates, these developments may have a material adverse impact on our business, financial condition, and results of operations.

Even if the FDA or a comparable authority in another jurisdiction grants accelerated approval for cabozantinib in one or more new indications or for one of our other product candidates, including zanzalintinib, such accelerated approval may be limited, imposing significant restrictions on the indicated uses, conditions for use, labeling, distribution, and/or production of the product and would impose requirements for post-marketing studies, including additional research and clinical trials, all of which may result in significant expense and limit our and our collaboration partners' ability to commercialize cabozantinib, zanzalintinib or our other product candidates in any new indications. In addition, some products approved under accelerated approval have encountered challenges with CMS coverage determinations. Failure to complete post-marketing requirements could significantly increase costs or delay, limit or ultimately restrict the commercialization of cabozantinib, zanzalintinib or another product candidate in the approved indication, or result in product withdrawal. Further, current or any future laws or executive orders governing FDA or foreign regulatory approval processes that may be enacted or executed could have a material adverse impact on our business, financial condition, and results of operations.

Risks Related to Financial Matters

Our profitability could be negatively impacted if expenses associated with our drug discovery, clinical development, business development and commercialization activities grow more quickly than the revenues we generate.

Although we reported net income of $521.3 million and $207.8 million for the fiscal years ended December 31, 2024 and 2023, respectively, we may not be able to maintain or increase profitability on a quarterly or annual basis, and we are unable to predict the extent of future profits or losses. The amount of our net profits or losses will depend, in part, on: the level of sales of CABOMETYX and COMETRIQ in the U.S.; our achievement of development, regulatory and commercial milestones, if any, under our collaboration agreements; the amount of royalties from sales of CABOMETYX and COMETRIQ outside of the U.S. under our collaboration agreements; other collaboration revenues; and the level of our expenses associated with our extensive drug discovery, clinical development, business development and commercialization activities, as well as our general business expansion plans. Our expected future expenses may also be increased by inflationary pressures, which could increase the costs of outside services, labor, raw materials and finished drug product. The introduction of or changes in tariffs or trade barriers, such as the enactment of tariffs on goods imported into the United States, including, but not limited to, the proposed tariffs on goods imported from China, Mexico and Canada (including raw materials and components used in our manufacturing processes), could also increase the costs of our finished drug product. We expect to continue to spend substantial amounts to fund the continued development of the cabozantinib franchise for additional indications and of zanzalintinib and our other product candidates, as well as the commercialization of our approved products. In addition, we intend to continue to expand our oncology product pipeline through our drug discovery efforts, including research collaborations, in-licensing arrangements and other strategic transactions that align with our oncology drug development, regulatory and commercial expertise, which efforts could involve substantial costs. To offset these costs in the future, we will need to generate substantial revenues. If these costs exceed our current expectations, or we fail to achieve anticipated revenue targets, our profitability and financial condition may be adversely affected and the market value of our common stock may decline.

Risks Related to Our Relationships with Third Parties

We rely on Ipsen and Takeda for the commercial success of CABOMETYX in its approved indications outside of the U.S., and we are unable to control the amount or timing of resources expended by these collaboration partners in the commercialization of CABOMETYX in its approved indications outside of the U.S.

We rely upon the regulatory, commercial, medical affairs, market access and other expertise and resources of our collaboration partners, Ipsen and Takeda, for commercialization of CABOMETYX in their respective territories outside of the U.S. We cannot control the amount and timing of resources that our collaboration partners dedicate to the commercialization of CABOMETYX, or to its marketing and distribution, and our ability to generate revenues from the commercialization of CABOMETYX by our collaboration partners depends on their ability to obtain and maintain regulatory approvals for, achieve market acceptance of, and to otherwise effectively market, CABOMETYX in its approved indications in their respective territories. If our collaboration partners are unable or unwilling to invest the resources necessary to commercialize CABOMETYX successfully in the EU, Japan, and other international territories where it has been approved, this could reduce the amount of revenue we are due to receive under these collaboration agreements, thus resulting in harm to our business and operations.

Our clinical, regulatory and commercial collaborations with major companies make us reliant on those companies for their continued performance and investments, which subjects us to a number of risks.

We have established clinical and commercial collaborations with leading biopharmaceutical companies for the development and commercialization of our products, and our dependence on these collaboration partners subjects us to a number of risks, including, but not limited to:

- our collaboration partners' decision to terminate our collaboration, or their failure to comply with the terms of our collaboration agreements and related ancillary agreements, either intentionally or as a result of negligence or other insufficient performance;
- our inability to control the amount and timing of resources that our collaboration partners devote to the development or commercialization of our products;
- the possibility that our collaboration partners may stop or delay clinical trials, fail to supply us on a timely basis with product required for a combination trial, or deliver product that fails to meet appropriate quality and regulatory standards;

- disputes that may arise between us and our collaboration partners that result in the delay or termination of the development or commercialization of our products or product candidates, or that diminish or delay receipt of the economic benefits we are entitled to receive under the collaboration, or that result in costly litigation or arbitration;
- the possibility that our collaboration partners may experience financial difficulties that prevent them from fulfilling their obligations under our agreements;
- our collaboration partners' inability to obtain regulatory approvals in a timely manner, or at all;
- our collaboration partners' failure to comply with legal and regulatory requirements relevant to the authorization, marketing, distribution and supply of our marketed products in the territories outside the U.S. where they are approved; and
- our collaboration partners' failure to properly maintain or defend our intellectual property rights or their use of our intellectual property rights or proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property rights or expose us to potential litigation.

If any of these risks materialize, we may not receive collaboration revenues or otherwise realize anticipated benefits from such collaborations, and our product development efforts and prospects for growth could be delayed or disrupted, all of which could have a material adverse impact on our business, financial condition and results of operations.

Our growth potential is dependent in part upon companies with which we have entered into research collaborations, in-licensing arrangements and similar business development relationships.

To expand our early-stage product pipeline, we have augmented our drug discovery activities with multiple research collaborations and in-licensing arrangements with other companies. Our dependence on our relationships with these research and in-licensing partners subjects us to numerous risks, including, but not limited to:

- our research and in-licensing partners' decision to terminate our relationship, or their failure to comply with the terms of our agreements, either intentionally or as a result of negligent performance;
- disputes that may arise between us and our research and in-licensing partners that result in the delay or termination of research and development activities with respect to any in-licensed assets or supporting technology platforms;
- the possibility that our research and in-licensing partners may experience financial difficulties that prevent them from fulfilling their obligations under our agreements;
- our research and in-licensing partners' failure to retain essential staff, which is crucial for fulfilling their obligations under our agreements;
- the possibility that our research and in-licensing partners' technology may be superseded or otherwise no longer be competitive;
- the possibility that our research and in-licensing partners may be acquired, and that any acquiring entity may not honor our partners' research commitments or otherwise fail to continue fulfilling their obligations under our agreements;
- our research and in-licensing partners' failure to properly maintain or defend their intellectual property rights or their use of third-party intellectual property rights or proprietary information in such a way as to invite litigation that could jeopardize or invalidate our license to develop these assets or utilize technology platforms;
- laws, regulations or practices imposed by countries or regions outside the U.S. that could impact or inhibit scientific research or the development of healthcare products by foreign competitors or otherwise disadvantage healthcare products made by foreign competitors, as well as general political or economic instability in those countries, any of which could complicate, interfere with or impede our relationships with our ex-U.S. research, development and in-licensing partners; and
- our research and in-licensing partners' failure to comply with applicable healthcare laws, as well as established laws and regulations related to Good Practice guidelines.

If any of these risks materialize, we may not be able to expand our product pipeline or otherwise realize a return on the resources we will have invested to develop these early-stage assets, which could have a material adverse impact on our financial condition and prospects for growth.

If third parties, upon which we rely to perform clinical trials for cabozantinib in new indications and for other new product candidates, do not perform as contractually required or expected, additional regulatory approvals may be delayed or may not be possible.

We do not have the ability to conduct clinical trials for cabozantinib or for new potential product candidates independently, so we rely on independent third parties for the performance of these trials, such as the U.S. federal government, third-party contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, or if the third parties must be replaced or if the quality or accuracy of the data they generate or provide is compromised due to their failure to adhere to our clinical trial or data security protocols or regulatory requirements or for other reasons, our preclinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for or commercialize cabozantinib beyond currently approved indications or obtain regulatory approval for zanzalintinib or our other product candidates. In addition, due to the complexity of our research initiatives, we may be unable to engage with third-party contract research organizations that have the necessary experience and sophistication to help advance our drug discovery efforts, which would impede our ability to identify, develop and commercialize our potential product candidates.

If third-party advisors we rely on to assist with our drug discovery and development efforts do not perform as expected, the expansion of our product pipeline may be delayed.

We work with scientific advisors at academic and other institutions, as well as third-party contractors in various locations throughout the world, who assist us in our research and development efforts, including in drug discovery and preclinical development strategy. These third parties are not our employees and may have other commitments or contractual obligations that limit their availability to us. Although these third-party scientific advisors and contractors generally agree not to do competing work, if a conflict of interest between their work for us and their work for another entity arises, we may lose their services. There has also been increased scrutiny surrounding the disclosures of payments made to medical researchers from companies in the pharmaceutical industry, and it is possible that the academic and other institutions that employ these medical researchers may prevent us from engaging them as scientific advisors and contractors or otherwise limit our access to these experts, or that the scientific advisors themselves may now be more reluctant to work with industry partners. Even if these scientific advisors and contractors with whom we have engaged intend to meet their contractual obligations, their ability to perform services may be impacted by increased demand for such services from other companies or by other external factors, such as reduced capacity to perform services. If we experience additional delays in the receipt of services, lose work performed by these scientific advisors and contractors or are unable to engage them in the first place, our discovery and development efforts with respect to the matters on which they were working or would work in the future may be significantly delayed or otherwise adversely affected.

We lack our own manufacturing and distribution capabilities necessary for us to produce materials required for certain preclinical activities and to produce and distribute our products for clinical development or for commercial sale, and our reliance on third parties for these services subjects us to various risks.

We do not operate our own manufacturing or distribution facilities for CMC development activities, preclinical, clinical or commercial production and distribution for our current products and new product candidates. Instead, we mostly rely on various third-party contract manufacturing organizations to conduct these operations on our behalf in accordance with cGMP. As our operations continue to grow in these areas, we are expanding internal CMC development laboratories to augment our external network focusing on our product candidates. We expect this to enable us to maximize application of our internal expertise and scientific know-how and advance our product candidates more efficiently and with greater technical precision, speed, agility and quality, while working in close collaboration with our expanding external manufacturing and supply chain network through additional third-party contract manufacturers, distributors and suppliers. To establish and manage our manufacturing network and supply chain requires a significant financial commitment, the creation of numerous third-party contractual relationships and continued oversight of these third parties to fulfill compliance with applicable legal and regulatory requirements, including the FDA's cGMP, the EC's Guidelines on GDP, as well as other stringent regulatory requirements enforced by the FDA or foreign regulatory agencies, as applicable. These third parties are also subject to routine inspections by the FDA and foreign regulatory agencies. Although we maintain significant resources to directly and effectively oversee the activities and relationships with the third parties in our network, we do not have direct control over their operations.

Our third-party contract manufacturers may not be able to produce or deliver material on a timely basis or manufacture material with the required quality standards, or in the quantity required to meet our preclinical, clinical

development and commercial needs and applicable regulatory requirements. Although we have not yet experienced significant production delays or seen significant impairment to our supply chain as a result of the ongoing hostilities in Eastern Europe and the Middle East or other global events, our third-party contract manufacturers, distributors and suppliers could experience operational delays due to lack of capacity or resources, facility closures and other hardships as a result of these types of global events, which could impact our supply chain by potentially causing delays to or disruptions in the supply of our preclinical, clinical or commercial products. If our third-party contract manufacturers, distributors and suppliers do not continue to supply us with our products or product candidates in a timely fashion and in compliance with applicable quality and regulatory requirements, or if they otherwise fail or refuse to comply with their obligations to us under our manufacturing, distribution and supply arrangements, we may not have adequate remedies for any breach. Furthermore, their failure to supply us could impair or preclude meeting commercial or clinical product supply requirements for us or our partners, which could delay product development and future commercialization efforts and have a material adverse impact on our business, financial condition and results of operations. In addition, through our third-party contract manufacturers and data service providers, we continue to provide serialized commercial products as required to comply with the DSCSA and its foreign equivalents where applicable. If our third-party contract manufacturers or data service providers fail to support our efforts to continue to comply with DSCSA and its foreign equivalents, as well as any future electronic pedigree requirements, we may face legal penalties or be restricted from selling our products.

Risks Related to Healthcare Regulatory and Other Legal Compliance Matters

We are subject to healthcare laws, regulations and enforcement; our failure to comply with those laws could have a material adverse impact on our business, financial condition and results of operations.

We are subject to federal and state healthcare laws and regulations, which laws and regulations are enforced by the federal government and the states in which we conduct our business. We also conduct clinical trial activities outside the United States and are therefore subject to applicable laws in the countries where those operations take place. Should our compliance controls prove ineffective at preventing or mitigating the risk and impact of improper business conduct or inaccurate reporting, we could be subject to enforcement of the following, including, without limitation:

- the federal AKS;
- federal Civil Monetary Penalties law, including the beneficiary inducement provisions;
- the Eliminating Kickbacks in Recovery Act;
- the FDCA and its implementing regulations;
- federal civil and criminal false claims laws, including the civil False Claims Act, and the Civil Monetary Penalties Law;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the HIPAA and its implementing regulation, as amended;
- state law equivalents of each of the above federal laws;
- state laws concerning contract pharmacy arrangements and related obligations of drug manufacturers;
- state and local laws and regulations that require drug manufacturers to file reports relating to marketing activities, payments and other remuneration and items of value provided to healthcare professionals and entities;
- state and federal pharmaceutical price and price reporting laws and regulations;
- European countries' national laws mandating public disclosure of transfers of value to healthcare professionals, healthcare organizations and other entities active in the healthcare sector, as well as requirements for prior review and/or approval of agreements with healthcare professionals; and
- laws and regulations in effect in foreign jurisdictions where drug manufacturers, or third party entities operating on behalf of drug manufacturers (including clinical research organizations), are conducting clinical trial activities.

In addition, we are subject to the Foreign Corrupt Practices Act, a U.S. law which regulates certain financial relationships with foreign government officials (which could include, for example, medical professionals employed by national healthcare programs) and its foreign equivalents, as well as federal and state consumer protection and unfair competition laws.

These federal and state healthcare laws and regulations govern drug marketing practices, including off-label promotion, and also impact our current and future business arrangements with third parties, including various healthcare

entities. If our operations are found, or even alleged, to be in violation of the laws described above or other governmental regulations that apply to us, we, or our officers or employees, may be subject to significant penalties, including administrative civil and criminal penalties, damages, fines, regulatory penalties, the curtailment or restructuring of our operations, exclusion from participation in Medicare, Medicaid and other federal and state healthcare programs, imprisonment, reputational harm, additional reporting requirements and oversight through a Corporate Integrity Agreement or other monitoring agreement, any of which would adversely affect our ability to sell our products and operate our business and also adversely affect our financial results. Furthermore, responding to any such allegation or investigation and/or defending against any such enforcement actions can be time-consuming and would require significant financial and personnel resources. Therefore, if any state or the federal government initiates an enforcement action against us, our business may be impaired, and even if we are ultimately successful in our defense, litigating these actions could result in substantial costs and divert the attention of management.

Enhanced governmental and private scrutiny over, or investigations or litigation involving, pharmaceutical manufacturer patient assistance programs and donations to patient assistance foundations created by charitable organizations could negatively impact our business practices, harm our reputation, divert the attention of management and increase our expenses.

To help patients afford our products, we have a patient assistance program and also make periodic donations to independent charitable foundations that help financially needy patients. These types of programs are designed to provide financial assistance to patients who might otherwise be unable to afford pharmaceuticals that they have been prescribed by their physicians and have become the subject of Congressional interest and enhanced government scrutiny. The HHS Office of Inspector General established guidelines permitting pharmaceutical manufacturers to make donations to charitable organizations that provide co-pay assistance to Medicare patients, provided that manufacturers meet certain specified compliance requirements. In the event we are found not to have complied with these guidelines and other laws or regulations respecting these arrangements, we could be subject to significant damages, fines, penalties or other criminal, civil or administrative sanctions or enforcement actions.

We also rely on a third-party hub provider and exercise oversight to monitor patient assistance program activities. Hub providers are generally hired by manufacturers to assist patients with insurance coverage, financial assistance and treatment support after the patients receive a prescription from their healthcare professional. For manufacturers of specialty pharmaceuticals (including our marketed products), the ability to have a single point of contact for their therapies helps ensure efficient medication distribution to patients. Accordingly, our hub activities are also subject to scrutiny and may create risk for us if not conducted appropriately. A variety of entities, including independent charitable foundations and pharmaceutical manufacturers, but not including our company, have received subpoenas from the U.S. Department of Justice (DOJ) and other enforcement authorities seeking information related to their patient assistance programs and reimbursement and other product support programs, and certain of these entities have entered into costly civil settlement agreements with DOJ and other enforcement authorities that include requirements to maintain complex corporate integrity agreements that impose significant reporting and other requirements. Should we or our hub providers receive a subpoena or other process, regardless of whether we are ultimately found to have complied with the regulations governing patient assistance and other product support programs, this type of government investigation could negatively impact our business practices, harm our reputation, divert the attention of management and increase our expenses.

We are subject to laws and regulations relating to privacy, data protection and the collection and processing of personal data. Failure to maintain compliance with these regulations could create additional liabilities for us.

The legislative and regulatory landscape for privacy and data protection continues to evolve in the U.S. and other jurisdictions around the world. For example, the CCPA went into operation in 2020 and affords California residents expanded privacy rights and protections, including civil penalties for violations and statutory damages under a private right of action for data security breaches. These protections were expanded by the CPRA, which became effective in January 2023. A rapidly-growing number of privacy laws in other states may also impact our operations, including both comprehensive and sector-specific legislation, and Congress has also considered additional federal privacy legislation. In addition, most healthcare professionals and facilities are subject to privacy and security requirements under HIPAA with respect to our clinical and commercial activities. Although we are not considered to be a covered entity or business associate under HIPAA, we could be subject to penalties if we use or disclose individually identifiable health information in a manner not authorized or permitted by HIPAA. Other countries also have, or are developing, laws governing the collection, use and transmission of personal information. For example, in the EU, the GDPR regulates the processing of personal data of individuals within the EU, even if, under certain circumstances, that processing occurs outside the EU, and also places restrictions on transfers of such data to countries outside of the EU, including the U.S. Should we fail to provide adequate

privacy or data security protections or maintain compliance with these laws and regulations, including the CCPA, as amended by the CPRA, as well as the GDPR, we could be subject to sanctions or other penalties, litigation, an increase in our cost of doing business and questions concerning the validity of our data processing activities, including clinical trials.

Risks Related to Our Information Technology and Intellectual Property

Data breaches and other cybersecurity incidents impacting our information technology operations and infrastructure could compromise our intellectual property or other sensitive information, damage our operations and cause significant harm to our business and reputation.

In the ordinary course of our business, we and our third-party service providers, such as contract research organizations, collect, maintain and transmit sensitive data on our networks and systems, including our intellectual property and proprietary or confidential business information (such as research data and personal information) and confidential information with respect to our customers, clinical trial patients and our collaboration partners. We outsource significant elements of our information technology infrastructure to third parties and, as a result, such third parties may or could have access to our confidential information. Additionally, we are vulnerable to data exfiltration, which is the loss of confidential and proprietary data in the event that persons with authorized access to our systems transfer our confidential and proprietary data outside our systems for their own use, evading our system safeguards and violating our policy restrictions on data transfer.

Artificial intelligence (AI) software is increasingly being used in the biopharmaceutical industry, including, in limited instances, by us. The misuse of AI-based software could result in inadvertent access and use of confidential information (including personal and proprietary data) of our employees, clinical trial participants, or other third parties, leading to the loss of trade-secrets or other intellectual property. As with many developing technologies, AI also presents risks related to misuse by outside threat actors who may try to gain unauthorized access to our systems and information. The secure maintenance of this information is critical to our business and reputation, and while we have enhanced and are continuing to enhance our cybersecurity efforts commensurate with the growth and complexity of our business, our systems and those of third-party service providers may be vulnerable to cybersecurity incidents or threats. In addition, we are heavily dependent on the functioning of our information technology infrastructure to carry out our business processes, such as external and internal communications or access to clinical data and other key business information. Accordingly, both inadvertent disruptions to this infrastructure and/or cyber-attacks could cause us to incur significant remediation or litigation costs, result in product development delays, disrupt critical business operations, expend key information technology resources and divert the attention of management.

Although the aggregate impact of cybersecurity incidents and threats, including cyber-attacks and data exfiltration, on our operations and financial condition has not been material to date, we and our third-party service providers have frequently been the target of threats of this nature and expect them to continue. Any future data breach and/or unauthorized access or disclosure of our information or intellectual property could compromise our intellectual property and expose our sensitive business information or sensitive business information of our collaboration partners, which may lead to significant liability for us. A data security breach could also lead to public exposure of personal information of our clinical trial patients, employees or others and result in harm to our reputation and business, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, including the GDPR, subject us to investigations and mandatory corrective action, or otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could disrupt our business, result in increased costs or loss of revenue, and/or result in significant financial exposure. Furthermore, the costs of maintaining or upgrading our cybersecurity systems (including the recruitment and retention of experienced information technology professionals, who are in high demand) at the level necessary to keep up with our expanding operations and prevent against potential attacks or other cybersecurity incidents are increasing, and despite our best efforts, our network security and data recovery measures and those of our third-party service providers may still not be adequate to protect against such security breaches and disruptions, which could cause material harm to our business, financial condition and results of operations.

If we are unable to adequately protect our intellectual property, third parties may be able to use our technology, which could adversely affect our ability to compete in the market.

Our success will depend in part upon our ability to obtain patents and maintain adequate protection of the intellectual property related to our technologies and products. The patent positions of biopharmaceutical companies, including our patent position, are generally uncertain and involve complex legal and factual questions. We will be able to protect our intellectual property rights from unauthorized use by third parties only to the extent that our technologies are

covered by valid and enforceable patents or are effectively maintained as trade secrets. We will continue to apply for patents covering our technologies and products as, where and when we deem lawful and appropriate. However, these applications may be challenged or may fail to result in issued patents. Our issued patents have been and may in the future be challenged by third parties as invalid or unenforceable under U.S. or foreign laws, or they may be infringed by third parties, and we are from time to time involved in the defense and enforcement of our patents or other intellectual property rights in a court of law, U.S. Patent and Trademark Office IPR review or reexamination proceeding, foreign opposition proceeding or related legal and administrative proceeding in the U.S. and elsewhere. The costs of defending our patents or enforcing our proprietary rights in post-issuance administrative proceedings and litigation can be substantial and the outcome can be uncertain. An adverse outcome may allow third parties to use our intellectual property without a license and/or allow third parties to introduce generic and other competing products, any of which would negatively impact our business. Third parties may also attempt to invalidate or design around our patents, or assert that they are invalid or otherwise unenforceable, and seek to introduce generic versions of cabozantinib. For example, we received Paragraph IV certification notice letters from MSN, Teva Pharmaceutical Industries Limited, Teva Pharmaceuticals Development, Inc. and Teva Pharmaceuticals USA, Inc. (individually and collectively referred to as Teva), Cipla, Ltd. and Cipla USA, Inc. (individually and collectively referred to as Cipla) and Sun concerning the respective ANDAs that each had filed with the FDA seeking approval to market their respective generic versions of CABOMETYX tablets. Should MSN, Teva, Cipla, Sun or any other third parties receive FDA approval of an ANDA or a 505(b)(2) NDA with respect to cabozantinib, it is possible that such company or companies could introduce generic versions of our marketed products before our patents expire if they do not infringe our patents or if it is determined that our patents are invalid or unenforceable, and the resulting generic competition could have a material adverse impact on our business, financial condition and results of operations.

In addition, because patent applications can take many years to issue, third parties may have pending applications, unknown to us, which may later result in issued patents that cover the production, manufacture, commercialization or use of our product candidates. Our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products. They may also be negatively impacted by the decisions of foreign courts, which could limit the protection contemplated by the original regulatory approval and our ability to thwart the development of competing products that might otherwise have been determined to infringe our intellectual property rights. Furthermore, others may independently develop similar or alternative technologies or design around our patents. In addition, our patents may be challenged or invalidated or may fail to provide us with any competitive advantages, if, for example, others were the first to invent or to file patent applications for closely related inventions.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the U.S., and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties and many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of the patent. Moreover, the Russian Federation has and may further limit protections on patents originating from certain countries (including the U.S.) in response to sanctions relating to the ongoing Russia-Ukraine war, and in general, the legal systems of certain countries, particularly certain developing countries, do not favor the aggressive enforcement of patent and other intellectual property protection, which makes it difficult to stop infringement. We also rely on trade secret protection for some of our confidential and proprietary information, and we are taking security measures to protect our proprietary information and trade secrets, particularly in light of recent instances of data loss and misappropriation of intellectual property in the biopharmaceutical industry. However, these measures may not provide adequate protection, and while we seek to protect our proprietary information by entering into confidentiality agreements with employees, partners and consultants, as well as maintain cybersecurity protocols within our information technology infrastructure, we cannot provide assurance that our proprietary information will not be disclosed, or that we can meaningfully protect our trade secrets. In addition, our competitors may independently develop substantially equivalent proprietary information or may otherwise gain access to our trade secrets.

Litigation or third-party claims of intellectual property infringement could require us to spend substantial time and money and adversely affect our ability to develop and commercialize products.

Our commercial success depends in part upon our ability to avoid infringing patents and proprietary rights of third parties and not to breach any licenses that we have entered into with regard to our technologies and the technologies of third parties. Other parties have filed, and in the future are likely to file, patent applications covering products and technologies that we have developed or intend to develop. If patents covering technologies required by our operations are issued to others, we may have to obtain licenses from third parties, which may not be available on commercially reasonable

terms, or at all, and may require us to pay substantial royalties, grant a cross-license to some of our patents to another patent holder or redesign the formulation of a product candidate so that we do not infringe third-party patents, which may be impossible to accomplish or could require substantial time and expense. In addition, we may be subject to claims that our employees or independent contractors have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers, or that they used or sought to use patent inventions belonging to their former employers. Furthermore, third parties may obtain patents that relate to our technologies and claim that use of such technologies infringes on their patents or otherwise employs their proprietary technology without authorization. Regardless of their merit, such claims could require us to incur substantial costs and divert the attention of management and key technical personnel in defending ourselves against any such claims or enforcing our own patents. In the event of any third party's successful claim of patent infringement or misappropriation of trade secrets, we may lose valuable intellectual property rights or personnel, which could impede or prevent the achievement of our product development goals, or we may be required to pay damages and obtain one or more licenses from these third parties, subjecting us to substantial royalty payment obligations. We may not be able to obtain these licenses on commercially reasonable terms, or at all. Defense of any lawsuit or failure to obtain any of these licenses could adversely affect our ability to develop and commercialize products.

Risks Related to Our Operations, Managing Our Growth and Employee Matters

If we are unable to manage our human capital needs, there could be a material adverse impact on our business, financial condition and results of operations, and our prospects may be adversely affected.

As we continue to grow our pipeline of product candidates, our clinical development organization and related functions may grow, which may place significant demands on our management and resources, and our current and planned personnel and operating practices may not be adequate to support such growth. To effectively manage our evolving human capital needs, we must continue to improve existing, and when necessary, implement new facilities, operational and financial systems, and procedures and controls, as well as train and manage our employee base, and there can be no assurance that we can do so effectively or avoid experiencing operating inefficiencies or control deficiencies. We continue to rely on our management personnel to oversee our operations, and retaining and recruiting qualified individuals is difficult. If we are unable to manage our human capital needs effectively, or if we are unsuccessful in retaining or recruiting qualified management personnel, there could be a material adverse impact on our business, financial condition and results of operations.

The loss of key personnel or the inability to retain or attract additional personnel could impair our ability to operate successfully.

We are highly dependent upon the principal members of our management, as well as clinical, commercial and scientific staff, the loss of whose services might adversely impact the achievement of our objectives. Also, we may not have sufficient personnel to execute our business plans. Retaining and, where necessary, recruiting qualified clinical, commercial, scientific and pharmaceutical operations personnel will be critical to support activities related to advancing the development programs for the cabozantinib franchise, zanzalintinib and our other product candidates, successfully executing upon our commercialization plan for the cabozantinib franchise and continuing our proprietary research and development efforts. Competition is intense for experienced clinical, commercial, scientific and pharmaceutical operations personnel, and we may be unable to retain or recruit such personnel with the expertise or experience necessary to allow us to successfully develop and commercialize our products. In addition, our reduction in workforce announced in January 2024 may adversely affect our ability to attract and retain employees. Furthermore, all of our employees are employed "at will" and, therefore, may leave our employment at any time.

Risks Related to Environmental and Product Liability

We use hazardous chemicals and biological materials in our business. Any claims relating to improper handling, storage or disposal of these materials could be time consuming and costly.

Our research and development processes involve the controlled use of hazardous materials, including chemicals and biological materials, and our operations can produce hazardous waste products. We cannot eliminate the risk of accidental contamination or discharge, or any resultant injury from these materials, and we may face liability under applicable laws for any injury or contamination that results from our use or the use by our collaboration partners or other third parties of these materials. Such liability may exceed our insurance coverage and our total assets, and in addition, we may be required to indemnify our collaboration partners against all damages and other liabilities arising out of our development activities or products produced in connection with our collaborations with them. Moreover, our continued

compliance with environmental laws and regulations may be expensive, and current or future environmental regulations may impair our research, development and production efforts.

We face potential product liability exposure far in excess of our limited insurance coverage.

We may be held liable if any product we or our collaboration partners develop or commercialize causes injury or is found otherwise unsuitable during product testing, manufacturing, marketing or sale. Regardless of merit or eventual outcome, product liability claims could result in decreased demand for our products and product candidates, injury to our reputation, withdrawal of patients from our clinical trials, product recall, substantial monetary awards to third parties and the inability to commercialize any products that we may develop in the future. We maintain limited product liability insurance coverage for our clinical trials and commercial activities. However, our insurance may not be sufficient to reimburse us for expenses or losses we may suffer. Moreover, if insurance coverage becomes more expensive, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability.

Risks Related to Our Common Stock

Our stock price has been and may in the future be highly volatile.

The trading price of our common stock has been highly volatile, and it may remain highly volatile or fluctuate substantially due to factors such as the following, many of which we cannot control:

- the announcement of FDA or other regulatory approval or non-approval, or delays in the FDA or other regulatory review process with respect to cabozantinib, zanzalintinib or our other product candidates, our collaboration partners' product candidates being developed in combination with either cabozantinib, zanzalintinib or our other product candidates, or our competitors' product candidates;
- the commercial performance of both CABOMETYX and COMETRIQ and the revenues we generate from those approved products, including royalties paid under our collaboration and license agreements;
- adverse or inconclusive results or announcements related to our or our collaboration partners' clinical trials or delays in those clinical trials;
- the timing of achievement of our clinical, regulatory, partnering, commercial and other milestones for the cabozantinib franchise, zanzalintinib or any of our other product candidates or programs;
- our ability to make future investments in the expansion of our pipeline through drug discovery, including future research collaborations, in-licensing arrangements and other strategic transactions;
- our ability to obtain the materials and services, including an adequate product supply for any approved drug product, from our third-party vendors or do so at acceptable prices;
- the timing and amount of expenses incurred for clinical development and manufacturing of cabozantinib, zanzalintinib and our other product candidates;
- actions taken by regulatory agencies, both in the U.S. and abroad, with respect to cabozantinib or our clinical trials for zanzalintinib or our other product candidates;
- unanticipated regulatory actions taken by the FDA as a result of changing FDA standards and practices concerning the review of product candidates, including approvals at earlier stages of clinical development or with lesser developed data sets and expedited reviews;
- the announcement of new products or clinical trial data by our competitors;
- the announcement of regulatory applications, such as MSN's, Teva's, Cipla's and Sun's respective ANDAs, seeking approval of generic versions of our marketed products;
- quarterly variations in our or our competitors' results of operations;
- changes in our relationships with our collaboration partners, including the termination or modification of our agreements, or other events or conflicts that may affect our collaboration partners' timing and willingness to develop, or if approved, commercialize our products and product candidates out-licensed to them;
- the announcement of an in-licensed product candidate or strategic acquisition;
- litigation, including intellectual property infringement and product liability lawsuits, involving us;
- changes in earnings estimates or recommendations by securities analysts, or financial guidance from our management team, and any failure to achieve the operating results projected by securities analysts or by our management team;

- the entry into new financing arrangements;
- developments in the biopharmaceutical industry;
- sales of large blocks of our common stock or sales of our common stock by our executive officers, directors and significant stockholders;
- the announcement of a repurchase of our common stock;
- additions and departures of key personnel or board members;
- the disposition of any of our technologies or compounds; and
- general market, macroeconomic and political conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

These and other factors could have a material adverse impact on the market price of our common stock. In addition, the stock markets in general, and the markets for biotechnology and pharmaceutical stocks in particular, have historically experienced significant volatility that has often been unrelated or disproportionate to the operating performance of particular companies. Likewise, as a result of significant changes in U.S. or global political and macroeconomic conditions, including inflation, fluctuating interest rates, as well as policies governing foreign trade (including tariffs) and healthcare spending and delivery, or the ongoing hostilities in Eastern Europe and the Middle East, the financial markets could continue to experience significant volatility that could also continue to negatively impact the markets for biotechnology and pharmaceutical stocks. These broad market fluctuations have adversely affected and may in the future adversely affect the trading price of our common stock. Excessive volatility may continue for an extended period of time following the date of this report.

In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been initiated. A securities class action suit against us could result in substantial costs and divert the attention of management, which could have a material adverse impact on our business, financial condition and results of operations.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent or deter attempts by our stockholders to replace or remove our current management, which could cause the market price of our common stock to decline.

Provisions in our corporate charter and bylaws may discourage, delay or prevent an acquisition of us, a change in control, or attempts by our stockholders to replace or remove members of our current Board of Directors. Because our Board of Directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. These provisions include:

- a prohibition on actions by our stockholders by written consent;
- the ability of our Board of Directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our Board of Directors; and
- advance notice requirements for director nominations and stockholder proposals.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Our disclosures related to environmental, social and governance matters subjects us to risks, including risks to our market perception and stock price.

The focus of governments, investors and other stakeholders on environmental, social and governance (ESG) practices and disclosures is constantly shifting and expectations in this area are evolving. Laws addressing ESG topics and regulations may change and affect mandatory disclosure, reporting and diligence requirements. We manage, track and report on our ESG initiatives, including in our Corporate Values & Sustainability Report or as may be required in our annual and quarterly reports. Our efforts to accomplish and report on these topics subjects us to risks, any of which could have a material adverse impact on our business, including specifically market perception and the market price of our common stock. Such risks may be outside of our control and the criteria by which our ESG practices and disclosures are assessed may

change due to the evolving regulatory requirements affecting ESG standards and disclosures, which could result in increased expectations for us with respect to ESG matters and cause us to undertake costly initiatives to satisfy such new criteria. Our failure or perceived failure to pursue or achieve our ESG objectives, or to maintain our ESG practices that meet evolving stakeholder expectations or expanding legal requirements, could have a material adverse impact on our market perception and stock price, as well as expose us to government enforcement actions and private litigation.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Risk Management and Strategy

We maintain a cybersecurity and information security program, which leverages best practices and standards. Risks from cybersecurity threats are regularly evaluated as part of our broader risk management activities and as a fundamental component of our internal control system. The scope of our evaluation encompasses risks that may be associated with both our internally managed IT systems and key business functions and sensitive data operated or managed by third-party service providers.

All employees receive cybersecurity training upon hire with annual or more frequent training thereafter with job-specific topic considerations. Our IT team engages third-party vendors to assist with providing timely cybersecurity threat alerts in addition to monitoring cybersecurity threats and our defenses against cyberattacks. This monitoring includes the proactive identification of vulnerabilities in our systems with threat intelligence. The employees within our broader IT team who specialize in cybersecurity operations (Security Ops Team) are responsible for coordinating and overseeing the activities of these third-party vendors.

Our Information Security Incident Response Plan (Response Plan) sets forth our response protocol for cybersecurity threats and cybersecurity incidents and is maintained by the Information Security Governance Committee (InfoSec Committee), which reviews the Response Plan on an annual basis. The InfoSec Committee is comprised of IT department leaders and members of our senior management team and is a subcommittee of our Ethics Committee, which provides reports to the Risk Committee of our Board of Directors. Our Response Plan is designed to provide a framework for how we identify, escalate and respond in the event of a data security breach and designates personnel who are responsible for these functions. Our Security Ops Team evaluates security alerts received from various sources, and any alert or threat that the Security Ops Team identifies as a cybersecurity incident (such as a data security breach) is promptly escalated to the InfoSec Committee for further assessment. Upon confirmation that a cybersecurity incident has occurred, our InfoSec Committee will establish an incident response team, which may include representatives from our internal departments, as well as outside legal counsel or other external cybersecurity consultants or service providers. The Incident Response Team aims to develop a coordinated response strategy, entailing risk containment, notification processes, system restoration, incident documentation and assessment, data preservation and forensic analysis.

The InfoSec Committee evaluates the implications of cybersecurity incidents to determine whether such incidents have had or are reasonably likely to have a material effect on our business strategy, financial condition, and results of operations. If a cybersecurity incident is deemed material by our InfoSec Committee, our Chief Financial Officer or General Counsel will notify the other members of our senior management team and the Chair of the Risk Committee of our Board of Directors as needed.

Cybersecurity threats, including as a result of any previous cybersecurity incidents, have not materially affected and we believe are not reasonably likely to materially affect us, including our business strategy, results of operations or financial condition. We and our third-party service providers have frequently been the target of cybersecurity threats and expect them to continue, and for an additional description of these cybersecurity risks and potential related impacts on us, see “Risk Factors” in Part I, Item 1A of this Annual Report on Form 10-K.

Governance

Board of Directors and Board Committees. In accordance with our Corporate Governance Guidelines, the Board of Directors, both directly and through its committees (including the Risk Committee) oversees the proper functioning of our risk management process. In particular, the Risk Committee assists the Board in its oversight of management’s

responsibility to assess, manage and mitigate risks associated with the Company's business and operational activities and to administer the Company's various compliance programs, in each case including data privacy and cybersecurity concerns. The Board and the Risk Committee each meet at regularly scheduled and special meetings throughout the year at which meetings management reports to the Board concerning the results of its risk management activities, as well as external factors that may change the levels of business risk to which we are exposed. Specifically, the Risk Committee receives regular updates from members of the InfoSec Committee or Ethics Committee, as often as necessary but at least once per year, with respect to our cybersecurity threats and responses to any cybersecurity incidents.

Management's Responsibilities. Management has implemented risk management structures, policies and procedures, and manages our risk exposure on a day-to-day basis. Accordingly, management assesses and responds to cybersecurity threats as part of our ongoing risk assessment and as an internal control over financial reporting. Our Security Ops Team directs our cybersecurity operations and risk responses. Members of the Security Ops Team then meet with the InfoSec Committee at least once every quarter to review and assess cybersecurity incidents and non-incident threats (and response measures undertaken) to determine if any adjustment to our cybersecurity risk assessment is required. At least once every year, members of the Security Ops Team and the Senior Vice President of Information Technology present our cybersecurity risk evaluation and threat response to the Ethics Committee and to the Risk Committee of the Board of Directors as needed. The InfoSec Committee is a subcommittee comprised of IT department leaders and members of the senior management team, including the Chief Executive Officer, Chief Financial Officer (who has oversight of our IT and cybersecurity activities), General Counsel (who has oversight of our compliance activities), and Senior Vice President of Information Technology (who has over 20 years of experience managing IT systems and personnel). The Security Ops Team reports to the Senior Vice President of Information Technology, as well as the broader InfoSec Committee. Members of the Security Ops team include IT professionals with extensive experience and education in technology and cybersecurity, and most have attained accreditation as Certified Information Systems Security Professionals, as granted by the International Information System Security Certification Consortium (also known as ISC2).

Item 2. Properties.

Our corporate headquarters is located in Alameda, California, where we lease approximately 610,000 square feet of office and laboratory space under multiple leases. During the third quarter of 2024, we recorded an impairment charge related to leased facilities we have no plan on utilizing in the near term. We are currently marketing approximately 215,000 square feet for sublease in Alameda, California. We have approximately 64,000 square feet of office and laboratory space in the Greater Philadelphia area. In 2025, we will be exiting approximately 40,000 square feet of our laboratory space in the Greater Philadelphia area as part of our restructuring plan approved in early 2024. We believe these leased facilities are sufficient to accommodate our current and near-term needs.

Item 3. Legal Proceedings.

The information required to be set forth under this Item 3 is incorporated by reference to "Note 12. Commitments and Contingencies – Legal Proceedings" of the "Notes to Consolidated Financial Statements" in Part II, Item 8 of this Annual Report on Form 10-K.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Our common stock has traded on the Nasdaq Global Select Market under the symbol "EXEL" since April 11, 2000.

Holders

On February 3, 2025, there were 305 holders of record of our common stock. The number of record holders is based upon the actual number of holders registered on our books at such date and does not include holders of shares in "street names" or persons, partnerships, associations, corporations or other entities identified in security position listings maintained by depository trust companies.

Dividends

Since inception, we have not paid dividends on our common stock. We currently do not plan to pay any cash dividends in the foreseeable future. Any future determination to pay dividends will be at the discretion of our Board of Directors.

Unregistered Sales of Equity Securities

There were no unregistered sales of equity securities by us during the year ended December 31, 2024.

Stock Repurchase Programs

In January 2024, our Board of Directors authorized a stock repurchase program to acquire up to $450.0 million of our outstanding common stock before the end of 2024. As of June 30, 2024, we completed the repurchase of 20.3 million shares of common stock for an aggregate purchase price of $450.0 million pursuant to our stock repurchase program.

In August 2024, our Board of Directors authorized a stock repurchase program to acquire up to $500.0 million of our outstanding common stock before the end of 2025. During the third and fourth quarter of 2024, we repurchased 6.1 million shares of common stock for an aggregate purchase price of $205.6 million. As of December 31, 2024, approximately $294.4 million remained available for future stock repurchases before the end of 2025.

Stock repurchases under the program may be made from time to time through a variety of methods, which may include open market purchases, in block trades, 10b5-1 trading plans, accelerated share repurchase transactions, exchange transactions, or any combination of such methods. The timing and amount of any stock repurchases under the stock repurchase program will be based on a variety of factors, including ongoing assessments of the capital needs of the business, alternative investment opportunities, the market price of our common stock and general market conditions. The program does not obligate us to acquire any particular amount of our common stock, and the stock repurchase program may be modified, suspended or discontinued at any time without prior notice.

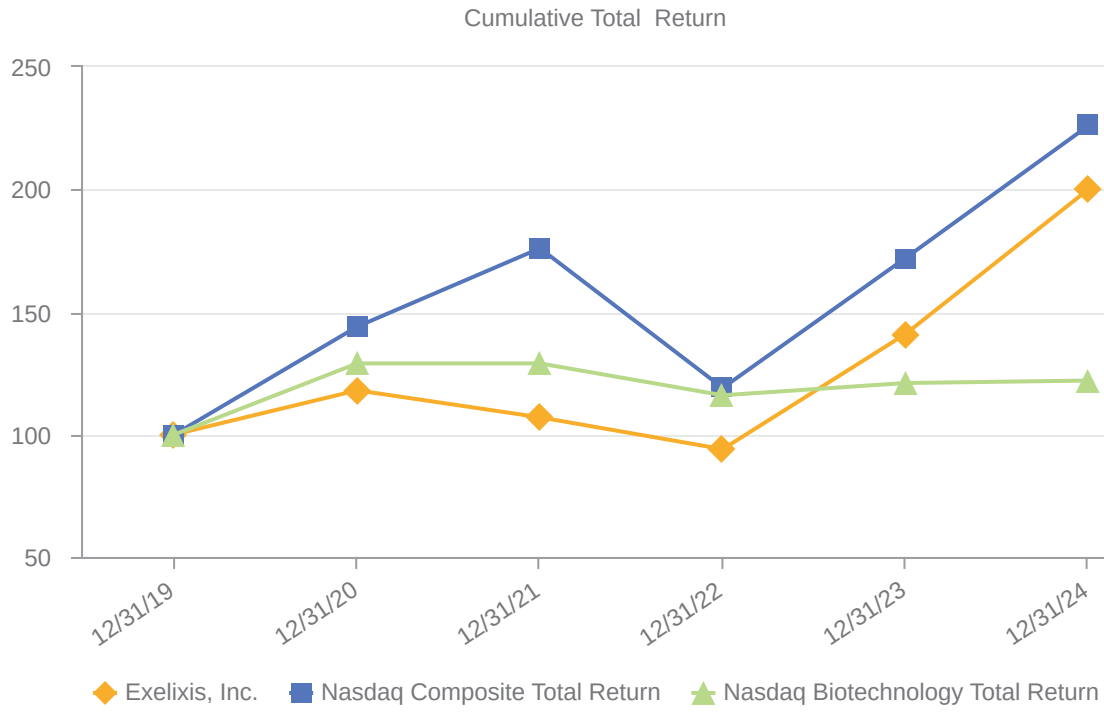
The following table summarizes the stock repurchase activity for the three months ended December 31, 2024 and the approximate dollar value of shares that may yet be purchased pursuant to our stock repurchase program (in thousands, except per share data):

	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Program	Approximate Dollar Value of Shares That May Yet Be Purchased Under the Program
September 28, 2024 - November 1, 2024	590	$ 29.00	590	$ 470,511
November 2, 2024 - November 29, 2024	2,390	$ 35.24	2,390	$ 386,277
November 30, 2024 - January 3, 2025	2,654	$ 34.64	2,654	$ 294,361
Total	5,634		5,634	

Performance

This performance graph shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities under that Section and shall not be deemed to be incorporated by reference into any filing of ours under the Securities Act of 1933, as amended.

The following graph compares, for the five-year period ended December 31, 2024, the cumulative total return for our common stock, the Nasdaq Composite Index and the Nasdaq Biotechnology Index. The graph assumes that $100 was invested on December 31, 2019 in each of our common stock, the Nasdaq Composite Total Return Index and the Nasdaq Biotechnology Total Return Index and assumes reinvestment of any dividends. The stock price performance on the following graph is not necessarily indicative of future stock price performance.



	Year Ended December 31,					
	2019	2020	2021	2022	2023	2024
Exelixis, Inc.	100	118	107	94	141	200
Nasdaq Composite Total Return	100	144	176	119	172	226
Nasdaq Biotechnology Total Return	100	129	129	116	121	122

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Some of the statements under "Management's Discussion and Analysis of Financial Condition and Results of Operations" are forward-looking statements. These statements are based on our current expectations, assumptions, estimates and projections about our business and our industry and involve known and unknown risks, uncertainties and other factors that may cause our company's or our industry's results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied in, or contemplated by, the forward-looking statements. Our actual results and the timing of events may differ significantly from the results discussed in the forward-looking statements. Factors that might cause such a difference include those discussed in "Item 1A. Risk Factors" as well as those discussed elsewhere in this Annual Report on Form 10-K. These and many other factors could affect our future financial and operating results. We undertake no obligation to update any forward-looking statement to reflect events after the date of this report.

Overview

We are an oncology company innovating next-generation medicines and combination regimens at the forefront of cancer care. We have produced four marketed pharmaceutical products, two of which are formulations of our flagship molecule, cabozantinib, and we are steadily advancing and evolving our product pipeline portfolio, including our lead asset zanzalintinib, currently the focus of an extensive late-stage clinical development program. With a rational and disciplined approach to investment, we are leveraging our internal experience and expertise, and the strength of strategic partnerships, to identify and pursue opportunities across the landscape of scientific modalities, including small molecules, biotherapeutics and ADCs.

Sales related to cabozantinib account for the majority of our revenues. Cabozantinib is an inhibitor of multiple tyrosine kinases, including MET, AXL, VEGF receptors and RET and has been approved by the FDA and in 67 other countries: as CABOMETYX® (cabozantinib) tablets for advanced RCC (both alone and in combination with BMS' nivolumab (OPDIVO®)), for previously treated HCC and for previously treated, RAI-refractory DTC; and as COMETRIQ® (cabozantinib) capsules for progressive, metastatic medullary thyroid cancer. For physicians treating these types of cancer, cabozantinib has become or is becoming an important medicine in their selection of effective therapies.

The other two products resulting from our discovery efforts are: COTELLIC® (cobimetinib), an inhibitor of MEK, approved as part of multiple combination regimens to treat specific forms of advanced melanoma and marketed under a collaboration with Genentech (a member of the Roche Group); and MINNEBRO® (esaxerenone), an oral, non-steroidal, selective blocker of the mineralocorticoid receptor, approved for the treatment of hypertension in Japan and licensed to Daiichi Sankyo Company, Limited.

We plan to continue leveraging our operating cash flows to advance a broad array of diverse biotherapeutics and small molecule programs for the treatment of cancer, as well as to support ongoing company-sponsored and externally sponsored trials evaluating cabozantinib. Furthest along in our pipeline is zanzalintinib, a novel, potent, third-generation oral TKI that targets VEGF receptors, MET and the TAM kinases (TYRO3, AXL and MER). Our zanzalintinib program includes a series of ongoing and planned pivotal trials to explore its therapeutic potential in CRC, RCC, SCCHN and NET, as well as earlier-stage trials. Our other pipeline programs in phase 1 development each have best-in-class potential and include: XL309, a small molecule inhibitor of USP1, which has emerged as a synthetic lethal target in the context of BRCA-mutated tumors; XB010, an ADC consisting of a MMAE payload conjugated to a human mAb targeting the tumor antigen 5T4; and XL495, a small molecule inhibitor of PKMYT1. We complement our internal drug discovery and development efforts by in-licensing investigational oncology assets or obtaining options to acquire other investigational oncology assets from third parties if those oncology assets demonstrate evidence of clinical success. Examples of this approach include XL309 and ADU-1805, a clinical-stage and potentially best-in-class human mAb that targets SIRPα.

Cabozantinib Franchise

The FDA first approved CABOMETYX in the U.S. as a monotherapy for previously treated patients with advanced RCC in April 2016, and then for previously untreated patients with advanced RCC in December 2017. In January 2021, the CABOMETYX label was expanded to include first-line advanced RCC in combination with nivolumab, which was the first CABOMETYX regimen approved for treatment in combination with an ICI. In addition to RCC, in January 2019, the FDA approved CABOMETYX for the treatment of patients with HCC previously treated with sorafenib, and then in September 2021, the FDA approved CABOMETYX for the treatment of adult and pediatric patients 12 years of age and older with locally advanced or metastatic DTC that has progressed following prior VEGF receptor-targeted therapy and who are RAI-refractory or ineligible.

The IRA introduced numerous substantial changes to drug pricing, reimbursement and access support in the U.S., including enabling the CMS to assert control over the prices of certain single-source drugs and biotherapeutics reimbursed under the Medicare Drug Price Negotiation Program. The IRA contains the limited small biotech exception. As of the date of this Annual Report on Form 10-K, CMS has informed us that we have qualified for the small biotech exception with respect to our cabozantinib franchise products through 2027 and we intend to apply to CMS to maintain the small biotech exception each year through 2030. Separately, in November 2023, CMS released final guidance on another program, the Part D Discount Program, which will require manufacturers to take on more of the beneficiary cost previously subsidized by the federal government through the application of increased drug discounts. We have since received notice from CMS that we qualify for the "specified small manufacturer" designation and are thereby eligible for a phase-in of the increased manufacturer discounts under the Part D Discount Program, from 2025 to 2031. We expect the increase in manufacturer

discount will be 1% in 2025 and will further increase according to a schedule set by CMS until we are required to pay the full 20% discount paid by other manufacturers in 2031.

To develop and commercialize cabozantinib outside the U.S., we have entered into license agreements with Ipsen and Takeda. To Ipsen, we granted the rights to develop and commercialize cabozantinib outside of the U.S. and Japan, and to Takeda we granted such rights in Japan. Both Ipsen and Takeda also contribute financially and operationally to the further global development and commercialization of the cabozantinib franchise in other potential indications, and we work closely with them on these activities. Utilizing its regulatory expertise and established international oncology marketing network, Ipsen has continued to execute on its commercialization plans for CABOMETYX, having received regulatory approvals and launched in multiple territories outside of the U.S., including in the EU, the United Kingdom and Canada, as a treatment for advanced RCC (both as a monotherapy and in combination with nivolumab) and for previously treated HCC and DTC indications. With respect to the Japanese market, Takeda received Manufacturing and Marketing Approvals from the Japanese PMDA for monotherapy CABOMETYX as a treatment of patients with curatively unresectable or metastatic RCC and as a treatment of patients with unresectable HCC that has progressed after cancer chemotherapy, as well as for CABOMETYX in combination with nivolumab as a treatment for unresectable or metastatic RCC.

We are also pursuing other indications for cabozantinib that have the potential to increase the number of cancer patients who could potentially benefit from this medicine. In August 2023, we announced positive results from CABINET, a phase 3 pivotal study that evaluated cabozantinib versus placebo in patients with NET who experienced progression after prior systemic therapy in two independently powered cohorts: one for patients with advanced pNET and another for patients with advanced epNET. The trial was unblinded and stopped early due to the dramatic improvement in efficacy with respect to the primary endpoint of PFS observed at interim analysis. Data from CABINET demonstrated that cabozantinib substantially prolonged PFS as assessed by blinded independent central review in both pNET and epNET cohorts, and that the safety profile of cabozantinib observed in the trial was consistent with its known safety profile. In August 2024, we announced that the FDA had accepted our sNDA seeking approval for cabozantinib to treat adult patients with previously treated, locally advanced/unresectable or metastatic, well- or moderately differentiated pNET or epNET, granted standard review in the U.S., and assigned a PDUFA target action date of April 3, 2025. The FDA also granted orphan drug designation to cabozantinib for the treatment of pNET. Detailed final results from CABINET were presented during the NETs and Endocrine Tumours Proffered Paper Session at the ESMO 2024 and were concurrently published in NEJM. In November 2024, we announced that our sNDA would be discussed at an ODAC meeting in March 2025; however, in January 2025, we announced that the FDA had notified us that our sNDA would no longer be the subject of discussion at an ODAC. CABINET was conducted by the Alliance through our CRADA with the NCI-CTEP, which along with our investigator-sponsored trial program, provides an avenue for independent investigations of cabozantinib. The Alliance presented results from a subgroup analysis of patients in the epNET cohort with advanced gastrointestinal NET in CABINET at the ASCO GI 2025.

Building on preclinical and clinical observations that cabozantinib in combination with ICIs may promote a more immune-permissive tumor environment, we have initiated several pivotal studies to further explore these combination regimens, including collaborations with Roche and BMS. In August 2023, we announced positive top-line results from CONTACT-02, a phase 3 pivotal trial sponsored by us and co-funded by Roche, evaluating the combination of cabozantinib and Roche's ICI, atezolizumab, versus a second NHT in patients with measurable, extra-pelvic mCRPC who have progressed after treatment with one prior NHT. The trial met one of two primary endpoints, demonstrating a statistically significant improvement in PFS in the predefined PFS intent-to-treat population (i.e., the first 400 randomized patients), and these data were presented at the American Society of Clinical Oncology Genitourinary Cancers Symposium in January 2024. For the second primary endpoint of OS, the final analysis for CONTACT-02, which was presented during the GU Tumours Proffered Paper Session at ESMO 2024, showed a trend that favored the combination of cabozantinib and atezolizumab but was not statistically significant. Of note, the trend in OS benefit was consistently observed in key subgroups, including in patients with liver metastases—a subgroup of mCRPC patients with the poorest prognosis in need of new treatment options, and one we anticipate will grow in the coming years. The safety profile observed in the trial was reflective of the known safety profiles for each single agent and was consistent with the known tolerability profile of approved ICI-TKI combinations in advanced solid tumors. We continue to evaluate the timing of a potential regulatory submission with the FDA. Both Ipsen and Takeda opted into and are co-funding the trial.

In August 2024, we announced the final analysis for the secondary endpoint of OS for COSMIC-313, a phase 3 pivotal trial evaluating the combination of cabozantinib, nivolumab and ipilimumab versus the combination of nivolumab and ipilimumab in patients with previously untreated advanced intermediate- or poor-risk RCC. At the final analysis, the experimental arm did not demonstrate an OS benefit over the control arm. Based on these results and the evolution of the

first-line RCC treatment landscape since this study was initiated in May 2019, Exelixis will not pursue marketing authorization for COSMIC-313. Data from the final analysis of OS in COSMIC-313 will be presented at the ASCO GU 2025.

Pipeline Activities

Zanzalintinib

Zanzalintinib is a novel, potent, third-generation oral TKI that targets VEGF receptors, MET and the TAM kinases (TYRO3, AXL and MER) implicated in cancer's growth and spread, and is our first in-house compound to enter the clinic following our re-initiation of drug discovery activities in 2017. We are evaluating zanzalintinib in a growing development program that builds on our prior experience with cabozantinib and targets indications with high unmet need. We have established collaborations and will continue to explore additional opportunities for novel combinations with zanzalintinib. To date, we have initiated two large phase 1b/2 clinical trials studying zanzalintinib as a monotherapy and in combination with ICIs (STELLAR-001 and STELLAR-002). Patient enrollment into STELLAR-001 was completed in 2023 and preliminary results from a randomized expansion cohort of patients with metastatic CRC were presented at the ASCO GI 2025. We anticipate initial clinical data readouts from STELLAR-002 in the first half of 2025. In addition, in December 2023, we initiated STELLAR-009 studying zanzalintinib in combination with AB521, an inhibitor of HIF-2α developed by Arcus; however, enrollment into STELLAR-009 was halted as of September 2024 following the joint decision between us and Arcus to wind down the study and end our clinical collaboration given the two companies' differing strategies with respect to potential TKI-HIF combination regimens to treat RCC.

We have also initiated three pivotal trials evaluating zanzalintinib in combination with ICIs. Our first such trial, STELLAR-303, was initiated in June 2022 and is evaluating zanzalintinib in combination with atezolizumab versus regorafenib in patients with metastatic, refractory non-microsatellite instability-high or non-mismatch repair-deficient CRC; we announced completion of enrollment into STELLAR-303 in August 2024, and preliminary results are expected in the second half of 2025. The second pivotal trial, STELLAR-304, was initiated in December 2022 and is evaluating zanzalintinib in combination with nivolumab versus sunitinib in previously untreated patients with advanced nccRCC; we anticipate completing enrollment into STELLAR-304 by mid-2025. In December 2023, we initiated STELLAR-305, a phase 2/3 pivotal trial evaluating zanzalintinib in combination with pembrolizumab, an anti-PD-1 ICI developed by Merck & Co., versus monotherapy pembrolizumab in patients with previously untreated PD-L1-positive recurrent or metastatic SCCHN; enrollment into STELLAR-305 is ongoing. We intend to initiate additional pivotal trials evaluating zanzalintinib across a broad array of future potential indications, including in STELLAR-311, a planned phase 3 pivotal trial evaluating zanzalintinib versus everolimus as a first oral therapy in patients with advanced NET, regardless of site of origin, which we anticipate initiating in the first half of 2025.

To further expand our exploration of the clinical potential of zanzalintinib, we entered into a clinical development collaboration with Merck to evaluate zanzalintinib in combination with KEYTRUDA® (pembrolizumab) in SCCHN and in combination with WELIREG® (belzutifan), Merck's oral HIF-2α inhibitor, in RCC. Under the collaboration, Merck will supply KEYTRUDA for our ongoing phase 3 STELLAR-305 trial in SCCHN. In addition, Merck will sponsor a phase 1/2 trial and two phase 3 pivotal trials in RCC; Merck will fund one of these phase 3 studies, and we will co-fund the phase 1/2 study and the other phase 3 study, as well as supply zanzalintinib and cabozantinib. We maintain all global commercial and marketing rights to zanzalintinib.

Biotherapeutics

Much of our drug discovery activity focuses on discovering and advancing various biotherapeutics that have the potential to become anti-cancer therapies, such as bispecific antibodies, ADCs and other innovative treatments. ADCs in particular present a unique opportunity for new cancer treatments, given their capabilities to target the delivery of anti-cancer drug payloads to specific cells expressing the target; this increased precision should minimize collateral impact on healthy tissues that do not express the target. This approach has been validated by multiple regulatory approvals of ADCs in the past several years. To facilitate the growth of our various biotherapeutics programs, we have established multiple research collaborations and in-licensing arrangements and have entered into other strategic transactions aimed at conserving capital and managing risks, collectively providing us access to antibodies, binders, payloads and conjugation technologies to generate next-generation ADCs or multispecific antibodies.

As part of our strategy to access clinical- or near-clinical-stage assets, we executed an exclusive option and license agreement and clinical development collaboration with Sairopa to develop ADU-1805. ADU-1805 is currently being evaluated in a phase 1 clinical trial in patients with advanced or metastatic refractory solid tumors, and enrollment is ongoing. Plans for ADU-1805 include investigating the compound's potential in combination with approved ICIs, including

pembrolizumab. In addition to the option deal with Sairopa, some of our active research collaborations for biotherapeutics programs are with:

- Adagene, which is focused on using Adagene's SAFEbody™ technology to develop novel masked ADCs or other innovative biotherapeutics with potential for improved therapeutic index;
- Catalent, which is focused on the discovery and development of multiple ADCs using Catalent's proprietary SMARTag site-specific bioconjugation technology; and
- Invenra, which is focused on the discovery and development of novel binders and multispecific antibodies for the treatment of cancer.

We have made significant progress under our research collaborations and in-licensing arrangements and believe we will continue to do so in 2025 and in future years. For example, in August 2024, we announced the initiation of a phase 1 clinical trial evaluating XB010, both as a monotherapy and in combination with pembrolizumab, in patients with advanced solid tumors, following the FDA's acceptance of our IND application, and enrollment is ongoing. XB010 is our first ADC advanced internally and consists of an MMAE payload conjugated to a mAb targeting the tumor antigen 5T4. XB010 was constructed using Catalent's SMARTag site-specific bioconjugation platform, and its 5T4-targeting mAb was discovered in collaboration with Invenra. Over the next two years, we also intend to advance four additional biotherapeutic candidates toward potential IND filings, and each of these candidates was discovered, in part, in connection with our research collaborations and in-licensing arrangements, including: XB628, a bispecific antibody that targets both PD-L1 and NKG2A; XB371, a next-generation TF-targeting ADC that consists of a topoisomerase inhibitor payload conjugated to a mAb targeting TF; XB064, a high-affinity mAb that targets ILT2; and XB033, an ADC targeting the tumor antigen IL13Rα2.

In August 2024, we announced that we will discontinue the development of XB002, our TF-targeting ADC, as part of our portfolio prioritization efforts. Based on available data, the compound is unlikely to improve upon tisotumab vedotin or other competitor TF-targeting ADCs currently in development. We plan to disclose data from the phase 1 JEWEL-101 study, evaluating XB002 in advance solid tumors, at a later date. We plan to reallocate resources to new pivotal trials with zanzalintinib, advancing XL309 and our growing pipeline.

Other Small Molecules

The knowledge and experience gained through our efforts to discover cabozantinib, cobimetinib and esaxerenone, each of which were approved by regulatory authorities and are commercially distributed, informs our current strategy for discovering and developing additional small molecules with the potential to treat cancer:

- XL309 is a potentially best-in-class small molecule inhibitor of USP1, a synthetic lethal target in the context of BRCA-mutated tumors. It is currently being evaluated in a phase 1 clinical trial as monotherapy and in combination with PARP1/2 inhibition in patients with advanced solid tumors; enrollment is ongoing. XL309 has potential in patients whose tumors are no longer responsive to PARPi, including ovarian, breast and prostate cancers. XL309 also has potential in combination with PARPi agents to deepen and prolong the response seen to PARPi, as well as to broaden the activity beyond that observed in patients with tumors that harbor a BRCA1/2 mutation.
- XL495 is an inhibitor of PKMYT1 with best-in-class potential to treat solid tumors due to its improved selectivity and pharmacokinetic profiles. In October 2024, we announced the initiation of a phase 1 clinical trial evaluating XL495, both as a monotherapy and in combination with select cytotoxic agents, in patients with advanced solid tumors, following the FDA's acceptance of our IND application.

Beyond these assets, we continue to make progress on multiple lead optimization programs for inhibitors of a variety of targets that we believe play significant roles in tumor growth, and we anticipate that some of these other programs could reach development candidate status in 2025 and beyond.

Future Expansion of our Pipeline

Increasing the number of novel anti-cancer agents in our pipeline is essential to our overall strategy and business goals. We are working to expand our oncology product pipeline through drug discovery efforts, which encompass our diverse biotherapeutics and small molecule programs exploring multiple modalities and mechanisms of action. This approach provides a high degree of flexibility with respect to target selection and modality of treatment and allows us to prioritize those targets that we believe have the greatest chance of becoming impactful therapeutics. As part of our strategy, our drug discovery activities have and will continue to include internal research, as well as external research collaborations, in-licensing arrangements and other strategic transactions that collectively leverage a wide range of technology platforms and assets and increase our probability of success. As of the date of this Annual Report on Form 10-K,

we expect to progress up to three new development candidates into preclinical development during 2025. We will continue to engage in pipeline expansion initiatives with the goal of discovering, acquiring and/or in-licensing promising investigational oncology assets and then further characterize and develop them utilizing our established preclinical and clinical development infrastructure.

2024 Business Updates and Financial Highlights

Business Updates

- In January 2024, we appointed Mary C. Beckerle, Ph.D. and S. Gail Eckhardt, M.D. to our Board of Directors. Dr. Beckerle currently serves as Chief Executive Officer of the Huntsman Cancer Institute and Distinguished Professor of Biological and Oncological Sciences at the University of Utah. Dr. Eckhardt currently serves as Associate Dean of Experimental Therapeutics at Baylor College of Medicine and Associate Director of Translational Research at the College's Dan L. Duncan Comprehensive Cancer Center.
- In January 2024, we announced that our Board of Directors had authorized a corporate restructuring plan (the 2024 Restructuring Plan) to reduce our workforce and rebalance our cost structure in alignment with our strategic priorities, including reducing real estate commitments and costs, and terminating certain licensing partnerships. The 2024 Restructuring Plan was initiated in the first quarter of 2024, and substantially completed in the second quarter of 2024.
- On March 27, 2024, we received a notice letter from Cipla asserting additional Paragraph IV Certifications arising from Cipla's amendment of its ANDA with the FDA. In May 2024, we announced entry into a settlement agreement with Cipla, which resolved patent litigation we brought in response to Cipla's ANDA. For a more detailed discussion of the Cipla matter, see "Note 12. Commitments and Contingencies – Legal Proceedings" of the "Notes to Consolidated Financial Statements" in Part II, Item 8 of this Annual Report on Form 10-K.
- In July 2024, Ipsen announced the expansion of our collaboration for the commercialization of cabozantinib to include pNET and epNET indications. Accordingly, Ipsen has sought marketing authorizations for CABOMETYX in these indications in certain territories outside of the U.S. and Japan, and in addition, Ipsen has opted into and is now co-funding the development costs for CABINET.
- In August 2024, we announced that the FDA had accepted our sNDA for CABOMETYX as a treatment for adult patients with previously treated, locally advanced/unresectable or metastatic, well- or moderately differentiated pNET and epNET, granted standard review and assigned a PDUFA target action date of April 3, 2025. In November 2024, we announced that our sNDA would be discussed at an ODAC meeting in March 2025; however, in January 2025, we announced that the FDA had notified us that our sNDA would no longer be the subject of discussion at an ODAC.
- In August 2024, we announced the initiation of a phase 1 clinical trial evaluating XB010, our first ADC advanced internally, following the FDA's earlier acceptance of our IND filing.
- In August 2024, we announced the achievement of a $150.0 million commercial milestone, recognized as license revenues from Ipsen during the second quarter of 2024, following Ipsen's achievement of $600.0 million in cumulative net sales of cabozantinib in its related license territory over four consecutive quarters, which milestone payment we received during the third quarter of 2024.
- In August 2024, we announced that our Board of Directors authorized the repurchase of up to $500 million of our common stock through the end of 2025, the third stock repurchase program undertaken by Exelixis since March 2023. Under this program, as of the end of fiscal year 2024, we have repurchased $205.6 million of our common stock, at an average price of $33.62 per share.
- In September 2024, we received a notice letter regarding an ANDA submitted to the FDA by Sun Pharmaceutical Industries Ltd. (Sun), including a Paragraph IV certification with respect to our U.S. Patent Nos. 8,877,776, 9,724,342, 10,034,873, 10,039,757, 11,091,439, 11,091,440, 11,098,015 and 11,298,349, the latest of which expires on February 10, 2032, requesting approval to market a generic version of CABOMETYX tablets prior to the expiration of the aforementioned patents. On October 30, 2024, we filed a complaint in the Delaware District Court for patent infringement against Sun asserting infringement of U.S. Patent Nos. 8,877,776, 11,091,440, and 11,098,015. On January 22, 2025, Sun filed its response to the complaint, alleging that the asserted claims of U.S. Patent No. 8,877,776, 11,091,439, 11,091,440 and 11098,015 are invalid and not infringed. Sun also filed counterclaims that, inter alia, seek a declaratory judgment that Sun's ANDA would not infringe any valid and enforceable claim of U.S. Patent Nos. 8,877,776, 11,091,439, 11,091,440, 11,098,015, 9,724,342, 10,034,873, 10,039,757, and 11,298,349. We have not yet responded to Sun's counterclaims.

- In October 2024, we announced a clinical development collaboration with Merck to support the evaluation of the combination of zanzalintinib and KEYTRUDA in SCCHN through our ongoing STELLAR-305 phase 3 pivotal trial, as well as future evaluations of the combination of zanzalintinib and WELIREG in RCC, including a phase 1/2 trial and two phase 3 pivotal trials to be sponsored by Merck.
- In October 2024, the United States District Court for the District of Delaware (the Delaware District Court) issued a ruling in our two consolidated patent lawsuits against MSN Pharmaceuticals, Inc. (individually and collectively with certain of its affiliates, including MSN Laboratories Private Limited, referred to as MSN, and such lawsuits collectively referred to as MSN II), rejecting MSN's invalidity challenge to each of U.S. Patents No. 11,091,439, 11,091,440 and 11,098,015, which expire January 15, 2030. The Delaware District Court had previously entered a stipulation that MSN's proposed ANDA product infringes these patents. The Delaware District Court also ruled that our U.S. Patent No. 11,298,349 is not invalid and that MSN's proposed ANDA product does not infringe this patent, which expires February 10, 2032. In accordance with these rulings, the Delaware District Court entered final judgment on October 23, 2024, that, should the FDA ultimately approve MSN's ANDA, the effective date of any such approval shall not be a date earlier than January 15, 2030, the expiration date of each of U.S. Patents No. 11,091,439, 11,091,440 and 11,098,015, subject to our potential additional regulatory exclusivity. On November 22, 2024 MSN noticed an appeal to the Court of Appeals for the Federal Circuit and we noticed a cross-appeal on November 26, 2024. The Delaware District Court judgment is also subject to appeal by either party. In February 2025, we received notice that MSN submitted to the FDA a Paragraph IV certification regarding our Orange Book patent: U.S. Patent No. 12,128,039. For a more detailed discussion of the MSN II litigation matter, see "Note 12. Commitments and Contingencies – Legal Proceedings" of the "Notes to Consolidated Financial Statements" in Part II, Item 8 of this Annual Report on Form 10-K.
- In October 2024, we announced the initiation of a phase 1 clinical trial evaluating XL495, our small molecule inhibitor of PKMYT1, following the FDA's earlier acceptance of our IND filing.
- In January 2025, preliminary results from a randomized expansion cohort of patients with metastatic CRC from STELLAR-001, and results from a subgroup analysis of patients in the epNET cohort with advanced gastrointestinal NET in CABINET, were presented at the ASCO GI 2025.

Financial Highlights

- Net product revenues for 2024 were $1,809.4 million, as compared to $1,628.9 million for 2023.
- Total revenues for 2024 were $2,168.7 million, as compared to $1,830.2 million for 2023.
- Research and development expenses for 2024 were $910.4 million, as compared to $1,044.1 million for 2023.
- Selling, general and administrative expenses for 2024 were $492.1 million, as compared to $542.7 million for 2023.
- Provision for income taxes for 2024 was $160.4 million, as compared to $49.8 million for 2023.
- Net income for 2024 was $521.3 million, or $1.80 per share, basic and $1.76 per share, diluted, as compared to $207.8 million, or $0.65 per share, basic and diluted, for 2023.

See *"Results of Operations"* below for a discussion of the detailed components and analysis of the amounts above.

Outlook, Challenges and Risks

We will continue to face numerous challenges and risks that may impact our ability to execute on our business objectives. In particular, for the foreseeable future, we expect our ability to generate sufficient cash flow to fund our business operations and growth will depend upon the continued commercial success of CABOMETYX, both alone and in combination with other therapies, as a treatment for the highly competitive indications for which it is approved, and possibly for other indications for which cabozantinib is currently being evaluated in potentially label-enabling clinical trials, if warranted by the data generated from these trials. However, we cannot be certain that the clinical trials we and our collaboration partners are conducting will demonstrate adequate safety and efficacy in these additional indications to receive regulatory approval in the major commercial markets where CABOMETYX is approved.

Even if the required regulatory approvals to market CABOMETYX for additional indications are achieved, we and our collaboration partners may not be able to commercialize CABOMETYX effectively and successfully in these additional indications. In addition, CABOMETYX will only continue to be commercially successful if private third-party and government payers continue to provide coverage and reimbursement. As is the case for all innovative pharmaceutical therapies, obtaining and maintaining coverage and reimbursement for CABOMETYX is becoming increasingly difficult, both within the U.S. and in foreign markets. In addition, healthcare policymakers in the U.S. continue to express concern over healthcare costs, and corresponding legislative and policy initiatives and activities have been launched aimed at increasing the

healthcare cost burdens borne by pharmaceutical manufacturers, as well as expanding access to, and restricting the prices and growth in prices of, pharmaceuticals.

Achievement of our business objectives will also depend on our ability to maintain a competitive position in the shifting landscape of therapeutic strategies for the treatment of cancer, which we may not be able to do. On an ongoing basis, we assess the constantly evolving landscape of other approved and investigational cancer therapies that could be competitive, or complementary in combination, with our products, and then we adapt our development strategies for the cabozantinib franchise and our pipeline product candidates accordingly, such as by modifying our clinical trials to include evaluation of our therapies with ICIs and other targeted agents. Even if our current and future clinical trials produce positive results sufficient to obtain marketing approval by the FDA and other global regulatory authorities, it is uncertain whether physicians will choose to prescribe regimens containing our products instead of competing products and product combinations in approved indications.

In the longer term, we may eventually face competition from potential manufacturers of generic versions of our marketed products, including the proposed generic versions of CABOMETYX tablets that are the subject of ANDAs submitted to the FDA by MSN, Teva, Cipla and Sun. The approval of any of these ANDAs and subsequent launch of any generic version of CABOMETYX could significantly decrease our revenues derived from the U.S. sales of CABOMETYX and thereby materially harm our business, financial condition and results of operations.

Separately, our research and development objectives may be impeded by the challenges of scaling our organization to meet the demands of expanded drug development, unanticipated delays in clinical testing and the inherent risks and uncertainties associated with drug discovery operations, especially on the global level. In connection with efforts to expand our product pipeline, we may be unsuccessful in discovering new potential cancer treatments or identifying appropriate candidates for in-licensing or acquisition.

Some of these challenges and risks are specific to our business, others are common to companies in the biopharmaceutical industry with development and commercial operations, and an additional category are macroeconomic, affecting all companies. For a more detailed discussion of challenges and risks we face, see “Risk Factors” in Part I, Item 1A of this Annual Report on Form 10-K.

Results of Operations

Impact of the Duration of Our Fiscal Year

We have adopted a 52- or 53-week fiscal year policy that generally ends on the Friday closest to December 31st. Fiscal year 2024, which was a 53-week fiscal year, ended on January 3, 2025; and fiscal year 2023, which was a 52-week fiscal year, ended on December 29, 2023. The 53-week fiscal year in 2024, as compared to the 52-week fiscal year in 2023, contributed to the year-over-year increases in certain revenues and expenses. For convenience, references in this report as of and for the fiscal years ended January 3, 2025 and December 29, 2023, are indicated as being as of and for the years ended December 31, 2024 and 2023, respectively. In fiscal year 2025, the annual period will end on January 2, 2026, and will be a 52-week fiscal year. The 52-week fiscal year in 2025 may result in a modest year-over-year impact on revenues and expenses, as compared to 2024.

This discussion and analysis generally addresses 2024 and 2023 items and year-over-year comparisons between 2024 and 2023. Discussions of 2022 items and year-over-year comparisons between 2023 and 2022 that are not included in this Annual Report on Form 10-K can be found in “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, filed with the SEC on February 6, 2024.

Revenues

Revenues by category were as follows (dollars in thousands):

	Year Ended December 31,		Percent Change
	2024	2023	
Net product revenues	$ 1,809,395	$ 1,628,879	11%
License revenues	349,244	178,635	96%
Collaboration services revenues	10,062	22,694	-56%
Total revenues	$ 2,168,701	$ 1,830,208	18%

Net Product Revenues

Gross product revenues, discounts and allowances, and net product revenues were as follows (dollars in thousands):

	Year Ended December 31,		Percent Change
	2024	2023	
Gross product revenues	$ 2,518,246	$ 2,272,533	11%
Discounts and allowances	(708,851)	(643,654)	10%
Net product revenues	$ 1,809,395	$ 1,628,879	11%

Net product revenues by product were as follows (dollars in thousands):

	Year Ended December 31,		Percent Change
	2024	2023	
CABOMETYX	$ 1,798,237	$ 1,614,942	11%
COMETRIQ	11,158	13,937	-20%
Net product revenues	$ 1,809,395	$ 1,628,879	11%

The increase in net product revenues for the year ended December 31, 2024, as compared to 2023, was primarily related to an 8.2% increase in the number of CABOMETYX units sold as a result of the FDA's approval of CABOMETYX in combination with nivolumab as a first-line treatment of patients with advanced RCC and, to a lesser extent, a 2.9% increase in the average net selling price of CABOMETYX. The increase in sales volume is largely driven by refills, reflecting the longer duration of therapy for this combination, and an increase in related market share reflecting the continued evolution of the metastatic RCC, HCC and DTC treatment landscapes.

We project our net product revenues may increase in fiscal year 2025, as compared to 2024, for similar reasons noted above.

We recognize product revenues net of discounts and allowances that are described in "Note 1. Organization and Summary of Significant Accounting Policies" of the "Notes to Consolidated Financial Statements" in Part II, Item 8 of this Annual Report on Form 10-K. Discounts and allowances have generally increased over time as the number of patients participating in government programs has increased and as the discounts given and rebates paid to government payers have also increased. The increase in the amount of discounts and allowances for the year ended December 31, 2024, as compared to 2023, was primarily the result of an increase in the volume of units sold, and the increase in utilization and dollar amount of chargebacks under the Federal Supply Schedule program.

We project our discounts and allowances may increase during fiscal year 2025 for similar reasons noted above.

License Revenues

License revenues include: (a) the recognition of the portion of milestone payments allocated to the transfer of intellectual property licenses for which it had become probable, in the related period, that a milestone would be achieved and a significant reversal of revenues would not occur in future periods; (b) royalty revenues; and (c) the profit on the U.S. commercialization of COTELLIC from Genentech.

See "Note 4. Collaborations and Business Development Activities—Cabozantinib Commercial Collaborations—*Performance Obligations and Transaction Prices for our Ipsen and Takeda Collaborations*" of the "Notes to Consolidated Financial Statements" in Part II, Item 8 of this Annual Report on Form 10-K for a discussion on the allocation of transaction price which impacts the proportion of milestone revenues allocated to license revenues and collaboration services revenues.

Milestone revenues, which are allocated between license revenues and collaboration services revenues, were $169.3 million for the year ended December 31, 2024, as compared to $15.0 million for 2023. Milestone revenues by fiscal year included the following:

- For the year ended December 31, 2024, milestone revenues included: (1) $150.0 million in license revenues recognized in connection with a commercial milestone from Ipsen upon its achievement of $600.0 million in cumulative net sales of cabozantinib over four consecutive quarters in its related Ipsen license territory; (2) $2.2 million in license revenues recognized in connection with a commercial milestone from Ipsen upon its achievement of CAD$30.0 million in cumulative net sales of cabozantinib over four consecutive quarters in Canada; and (3) $11.4 million in revenues related to a $12.5 million regulatory milestone from Ipsen upon submission of a variation application the EMA for evaluating cabozantinib versus placebo in patients with either advanced pNET or advanced epNET who experienced progression after prior systematic therapy.
- For the year ended December 31, 2023, $10.0 million in revenues was recognized in connection with a commercial milestone of $11.0 million from Takeda upon their achievement of $150.0 million of cumulative net sales of cabozantinib in Japan.

Due to uncertainties surrounding the timing and achievement of development, regulatory and commercial milestones, it is difficult to predict the timing of future milestones revenues; consequently, milestones may vary significantly from period to period.

Royalty revenues increased primarily as a result of an increase in Ipsen's net sales of cabozantinib outside of the U.S. and Japan. Ipsen royalties were $154.0 million for the year ended December 31, 2024, as compared to $135.8 million for 2023. Ipsen's net sales of cabozantinib have continued to grow since the first commercial sale of CABOMETYX in the Ipsen territories in 2016, primarily due to regulatory approvals in new territories, including regulatory approval in the EU for the combination therapy of CABOMETYX and nivolumab received in March 2021. Royalty revenues for the year ended December 31, 2024 also included $12.9 million, as compared to $12.7 million for 2023, related to Takeda's net sales of cabozantinib. Takeda's net sales of cabozantinib have continued to grow since Takeda's first commercial sale of CABOMETYX in Japan in 2020; however, royalty revenues during the year ended December 31, 2024 were unfavorably impacted by foreign currency rate fluctuations, as compared to 2023. As of December 31, 2024, CABOMETYX is approved and commercially available in 67 countries outside of the U.S.

Our share of profits on the U.S. commercialization of COTELLIC under our collaboration agreement with Genentech was $10.6 million for the year ended December 31, 2024, as compared to $13.0 million for 2023. We also earned royalty revenues on ex-U.S. net sales of COTELLIC by Genentech of $3.0 million for the year ended December 31, 2024, as compared to $3.9 million for 2023.

We project our license revenues may decrease in fiscal year 2025, as compared to 2024, as a result of the anticipated achievement of fewer milestones in 2025, partially offset by an increase in royalty revenues related to an increase in product sales by Ipsen and Takeda.

Collaboration Services Revenues

Collaboration services revenues include the recognition of deferred revenues for the portion of upfront and milestone payments that have been allocated to research and development services performance obligations, development cost reimbursements earned under our collaboration agreements and product supply revenues, which are net of product supply costs and the royalties we pay to Royalty Pharma on sales by Ipsen and Takeda of products containing cabozantinib.

Development cost reimbursements were $25.8 million for the year ended December 31, 2024, as compared to $35.6 million for 2023. The decrease in development cost reimbursements during the year ended December 31, 2024 were primarily attributable to decreases in spending on the CONTACT-02, CheckMate -9ER and COSMIC-021 studies, partially offset by Ipsen's decision to opt-in and co-fund CABINET development costs in the second quarter of 2024, which includes a cumulative catch-up for Ipsen's share of global development costs incurred since the beginning of the study and through the opt-in date.

Collaboration services revenues were reduced by $21.3 million and $19.2 million for the years ended December 31, 2024 and 2023, respectively, to account for the 3% royalty we are required to pay on the net sales by Ipsen and Takeda of any product containing cabozantinib. As royalty generating sales of cabozantinib by Ipsen and Takeda have increased as described above, our royalty payments have also increased.

We project our collaboration services revenues may decrease in fiscal year 2025, as compared to 2024, primarily as a result of a decrease in development cost reimbursement revenues, and uncertainties regarding the timing and achievement of development, regulatory, and commercial milestone revenues.

Cost of Goods Sold

The cost of goods sold and our gross margins were as follows (dollars in thousands):

	Year Ended December 31,		Percent Change
	2024	2023	
Cost of goods sold	$ 76,216	$ 72,547	5%
Gross margin %	96%	96%	

Cost of goods sold is related to our product revenues and consists of a 3% royalty payable on U.S. net sales of any product containing cabozantinib, as well as the cost of inventory sold, indirect labor costs, write-downs related to expiring, excess and obsolete inventory, and other third-party logistics costs. The increase in cost of goods sold for the year ended December 31, 2024, as compared to 2023, was primarily due to the increase in royalties as a result of increased U.S. CABOMETYX sales, partially offset by a decrease in certain period costs. We project our gross margin in 2025 will remain consistent with fiscal year 2024.

Research and Development Expenses

We do not track fully burdened research and development expenses on a project-by-project basis. We group our research and development expenses into three categories: (1) development; (2) drug discovery; and (3) other research and development. Our development group leads the development and implementation of our clinical and regulatory strategies and prioritizes disease indications in which our compounds are being or may be studied in clinical trials. Development expenses include license and other collaboration costs, primarily composed of upfront license fees, development milestones and other payments associated with our clinical-stage in-licensing collaboration programs, clinical trial costs, personnel expenses, consulting and outside services and other development costs, including manufacturing costs of our drug development candidates. Our drug discovery group utilizes a variety of technologies, including in-licensed technologies, to enable the rapid discovery, optimization and extensive characterization of lead compounds and biotherapeutics such that we are able to select development candidates with the best potential for further evaluation and advancement into clinical development. Drug discovery expenses include license and other collaboration costs primarily composed of upfront license fees, research funding commitments, option exercise fees, development milestones and other payments associated with our in-licensing collaboration programs in preclinical development stage. Other drug discovery costs include personnel expenses, consulting and outside services and laboratory supplies. Other research and development expenses include the allocation of general corporate costs to research and development services and development cost reimbursements in connection with certain of our collaboration arrangements.

Research and development expenses by category were as follows (dollars in thousands):

	Year Ended December 31,		Percent Change
	2024	2023	
Development:			
Clinical trial costs	$ 284,335	$ 281,338	1%
Personnel expenses	183,951	167,879	10%
License and other collaboration costs	45,000	80,036	-44%
Consulting and outside services	46,086	43,586	6%
Other development costs	106,475	96,401	10%
Total development	665,847	669,240	-1%
Drug discovery:			
License and other collaboration costs	24,172	92,970	-74%
Other drug discovery costs	70,670	122,115	-42%
Total drug discovery	94,842	215,085	-56%
Stock-based compensation	30,670	34,320	-11%
Other research and development	119,049	125,426	-5%
Total research and development expenses	$ 910,408	$ 1,044,071	-13%

In addition, we track our external clinical trial costs by product and product candidate and by scientific modalities, which are categorized as small molecule and biotherapeutics programs. Small molecule clinical development for the reported periods was primarily composed of cabozantinib and zanzalintinib. Biotherapeutics clinical development for the reported periods was primarily composed of XB002 and XB010.

Clinical trial costs by scientific modalities, by product and by product candidate were as follows (dollars in thousands):

	Year Ended December 31,		Percent Change
	2024	2023	
Small molecules:			
Zanzalintinib	$ 148,808	$ 136,383	9%
Cabozantinib	70,755	105,318	-33%
Other small molecules	20,232	9,115	122%
Total small molecules	239,795	250,816	-4%
Biotherapeutics	44,540	30,522	46%
Total clinical trial costs	$ 284,335	$ 281,338	1%

The decrease in research and development expenses for the year ended December 31, 2024, as compared to 2023, was primarily related to decreases in license and other collaboration costs and other drug discovery costs, partially offset by an increase in other development costs, primarily related to manufacturing costs to support Exelixis' development candidates and clinical trial costs.

Development-related license and other collaboration costs decreased for the year ended December 31, 2024, as compared to 2023, primarily due to an $80.0 million upfront payment made upon the execution of the exclusive license agreement with Insilico in 2023, partially offset by development milestone achievement in our clinical-stage in-licensing collaboration programs. Drug discovery-related license and other collaboration costs decreased for the year ended December 31, 2024, as compared to 2023, primarily due to lower development milestone achievement in our preclinical development stage in-licensing collaboration programs, lower upfront fees and lower research funding. Other drug discovery costs decreased for the year ended December 31, 2024, as compared to 2023, primarily due to decreases in personnel expenses, consulting and outside services, and laboratory supplies. Clinical trial costs, which include services performed by third-party contract research organizations and other vendors who support our clinical trials, increased for

year ended December 31, 2024, as compared to 2023, primarily due to higher costs associated with studies evaluating zanzalintinib, XB010, XL309 and XL495, partially offset by lower costs associated with cabozantinib studies.

In addition to reviewing the three categories of research and development expenses described above, we principally consider qualitative factors in making decisions regarding our research and development programs. These factors include enrollment in clinical trials for our product candidates, preliminary data and final results from clinical trials, the potential market indications and overall clinical and commercial potential for our product candidates, and competitive dynamics. We also make our research and development decisions in the context of our overall business strategy.

We project that clinical trial costs may continue to increase with higher costs associated with various studies evaluating zanzalintinib, XL309, XL495, and XB628, partially offset by decreases in costs associated with cabozantinib and XB002.

To continue growing our pipeline, we are prioritizing investment in new molecules that are clinically differentiated with the potential to improve the standard of care for our cancer patients, including current and planned clinical trial programs evaluating zanzalintinib, XL309, XL495, and XB010. We are working to expand our oncology product pipeline through drug discovery efforts, which encompass our diverse biotherapeutics and small molecule programs exploring multiple modalities and mechanisms of action. This approach provides a high degree of flexibility with respect to target selection and allows us to prioritize those targets that we believe have the greatest chance of yielding impactful therapeutics. As part of our strategy, our drug discovery activities have included and continue to include internal research, as well as external research collaborations, in-licensing arrangements and other strategic transactions that collectively incorporate a wide range of technology platforms and assets and increase our probability of success. As of the date of this Annual Report on Form 10-K, we expect to progress up to three new development candidates into preclinical development in 2025. We will continue to engage in pipeline expansion initiatives with the goal of acquiring and in-licensing promising investigational oncology assets and then further characterize and develop them utilizing our established preclinical and clinical development infrastructure.

We project our research and development expenses may increase for fiscal year 2025, as compared to the prior year, primarily driven by increases in license and other collaboration costs and clinical trial costs, including the current and planned trials evaluating zanzalintinib, XL309, XL495, and XB010, partially offset by lower manufacturing costs.

A discussion of the risks and uncertainties with respect to our research and development activities, and the consequences to our business, financial position, and growth prospects can be found in “Risk Factors” in Part I, Item 1A of this Annual Report on Form 10-K.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were as follows (dollars in thousands):

	Year Ended December 31,		Percent Change
	2024	2023	
Selling, general and administrative expenses[(1)]	$ 428,962	$ 470,680	-9%
Stock-based compensation	63,166	72,025	-12%
Total selling, general and administrative expenses	$ 492,128	$ 542,705	-9%

[(1)] Excludes stock-based compensation allocated to selling, general and administrative expenses.

Selling, general and administrative expenses consist primarily of personnel expenses, stock-based compensation, marketing costs and certain other administrative costs.

The decrease in selling, general and administrative expenses for the year ended December 31, 2024, as compared to 2023, was primarily due to decreases in corporate giving, legal and advisory fees related to the 2023 proxy contest and a reduction in activities related to litigation, technology costs and stock-based compensation expenses, partially offset by an increase in personnel expenses.

We project our selling, general and administrative expenses may increase in fiscal year 2025, as compared to 2024, as a result of an increase in the Branded Prescription Drug Fee due to higher revenues and an increase in marketing

activities in support of the anticipated commercial launch of CABOMETYX for the treatment of patients with either advanced pNET or advanced epNET who experienced progression after prior systemic therapy.

Impairment of Long-Lived Assets

Impairment of long-lived assets for the year ended December 31, 2024, relates to certain leased facilities at our Alameda campus. During fiscal year 2024, we listed certain buildings for sublease. As a result, we assessed the impacted asset groups for impairment and concluded that the related right-of-use assets and leasehold improvements were not fully recoverable and recognized a $51.7 million non-cash impairment charge. See "Note 12. Commitments and Contingencies" of the "Notes to Consolidated Financial Statements" in Part II, Item 8 of this Annual Report on Form 10-K for additional information.

Impairment of long-lived assets were as follows (dollars in thousands):

	Year Ended December 31,		Percent Change
	2024	2023	
Impairment of long-lived assets	$ 51,672	$ —	n/a

Restructuring Expenses

Restructuring expenses resulted from the execution of the 2024 Restructuring Plan to reduce our workforce and rebalance our cost structure in alignment with our strategic priorities. Restructuring expenses consist of severance and employee-related costs, asset impairment, and contract termination costs. We incurred the majority of the charges related to the 2024 Restructuring Plan during the first quarter of 2024. See "Note 13. Restructuring" of the "Notes to Consolidated Financial Statements" in Part II, Item 8 of this Annual Report on Form 10-K for additional information.

Restructuring expenses were as follows (dollars in thousands):

	Year Ended December 31,		Percent Change
	2024	2023	
Restructuring expenses	$ 33,660	$ —	n/a

Non-Operating Income

Non-operating income was as follows (dollars in thousands):

	Year Ended December 31,		Percent Change
	2024	2023	
Interest income	$ 77,156	$ 86,543	-11%
Other income (expense), net	(133)	93	n/a
Non-operating income	$ 77,023	$ 86,636	-11%

The decrease in non-operating income for the year ended December 31, 2024, as compared to 2023, was primarily the result of a decrease in interest income due to lower average interest-bearing investment balances, partially offset by higher average interest rates.

Provision for Income Taxes

The provision for income taxes and the effective tax rates were as follows (dollars in thousands):

	Year Ended December 31,		Percent Change
	2024	2023	
Provision for income taxes	$ 160,373	$ 49,756	222%
Effective tax rate	23.5%	19.3%	

The increase in provision for income taxes for the year ended December 31, 2024, as compared to 2023, was primarily due to an increase in pre-tax income. The effective tax rate for the year ended December 31, 2024 differed from the U.S. federal statutory rate of 21% primarily due to state taxes, partially offset by the generation of federal tax credits. The effective tax rate for the year ended December 31, 2023 differed from the U.S. federal statutory rate of 21% primarily due to the generation of federal tax credits, partially offset by non-deductible executive compensation. We project that our effective tax rate may be between 21% and 22% in fiscal year 2025.

Liquidity and Capital Resources

As of December 31, 2024, we had $1.7 billion in cash, cash equivalents and marketable securities, as compared to $1.7 billion as of December 31, 2023. We anticipate that the aggregate of our current cash and cash equivalents, marketable securities available for operations, net product revenues and collaboration revenues will enable us to maintain our operations for at least 12 months and thereafter for the foreseeable future.

Our primary cash requirements for operating activities, which we project will increase in fiscal 2025 as compared to fiscal year 2024, are for: employee related expenditures; payments related to our collaboration and development programs; income tax payments; royalty payments on our net product sales; cash payments for inventory; rent payments for our leased facilities and contract manufacturing payments.

The Tax Cuts and Jobs Act, signed into law on December 22, 2017, modified the tax treatment of research and development expenditures beginning in fiscal year 2022. Research and development expenditures are no longer currently deductible but instead must be amortized ratably over five years for domestic expenditures or 15 years for foreign expenditures. As a result, we generated a higher federal income tax liability in fiscal year 2024, which required higher estimated federal tax payments by the end of 2024. We will realize a reduction of our federal income tax liability in future years as the capitalized research and development expenditures are amortized for tax purposes.

Our primary sources of operating cash are: cash collections from customers related to net product revenues, which we project may increase for fiscal year 2025, as compared to 2024; cash collections related to milestones achieved and royalties earned from our commercial collaboration arrangements with Ipsen, Takeda and others; and cash collections for cost reimbursements under certain of our development programs with Ipsen and Takeda which we project may decrease in 2025, as compared to 2024. The timing of cash generated from commercial collaborations and cash payments required for in-licensing collaborations relative to upfront license fee payments, research funding commitments, cost reimbursements, exercise of option payments and other contingent payments such as development milestone payments may vary from period to period.

We project that we may continue to spend significant amounts of cash to fund the development of product candidates in our pipeline, including zanzalintinib, XL309, XL495, XB010, and XB628, and the development and commercialization of cabozantinib. In addition, we may continue to expand our oncology product pipeline through additional research collaborations, in-licensing arrangements and other strategic transactions that align with our oncology drug development, regulatory and commercial expertise.

In January 2024, our Board of Directors authorized the repurchase of up to $450.0 million of our common stock before the end of 2024. As of June 30, 2024, we completed the repurchase of 20.3 million shares of common stock for an aggregate purchase price of $450.0 million pursuant to our stock repurchase program. In August 2024, our Board of Directors authorized a stock repurchase program to acquire up to $500.0 million of our outstanding common stock before the end of 2025. Under this program, during the third and fourth quarter of 2024, we repurchased 6.1 million shares of common stock for an aggregate purchase price of $205.6 million. As of December 31, 2024, approximately $294.4 million remained available for future stock repurchases before the end of 2025. Stock repurchases under this program may be made from time to time through a variety of methods, which may include open market purchases, in block trades, Rule 10b5-1 trading plans, accelerated share repurchase transactions, exchange transactions, or any combination of such methods.

The timing and amount of any stock repurchases under the stock repurchase program will be based on a variety of factors, including ongoing assessments of the capital needs of the business, alternative investment opportunities, the market price of Exelixis' common stock and general market conditions.

Financing these activities could materially impact our liquidity and capital resources and may require us to incur debt or raise additional funds through the issuance of equity. Furthermore, even though we believe we have sufficient

funds for our current and future operating plans, we may choose to incur debt or raise additional funds through the issuance of equity based on market conditions or strategic considerations.

Sources and Uses of Cash (dollars in thousands):

	Year Ended December 31,		Percent Change
	2024	2023	
Working capital	$ 1,063,810	$ 923,681	15%
Cash, cash equivalents and marketable securities	$ 1,748,567	$ 1,724,019	1%

Working capital: The increase in working capital as of December 31, 2024, as compared to December 31, 2023, was primarily due to the favorable impact to our net current assets resulting from our increase in net product revenues and collaboration revenues, including a total of $164.7 million in milestone payments earned from Ipsen and reduction of the duration of our investments, partially offset by repurchases of our common stock. In the future, our working capital may be impacted by one of these factors or other factors, the amounts and timing of which are variable.

Cash, cash equivalents and marketable securities: Cash and cash equivalents primarily consist of deposits at major banks, money market funds, commercial paper and other securities with original maturities 90 days or less. Marketable securities primarily consist of debt securities available-for-sale and certificates of deposit. For additional information regarding our cash, cash equivalents and marketable securities, see “Note 5. Cash and Marketable Securities,” of the “Notes to Consolidated Financial Statements” in Part II, Item 8 of this Annual Report on Form 10-K. The increase in cash, cash equivalents and marketable securities at December 31, 2024, as compared to December 31, 2023, was primarily due to cash inflows generated by our operations from sales of our products and our commercial collaboration arrangements, including $164.7 million in cash received from Ipsen for regulatory and commercial milestone payments earned, partially offset by cash payments to repurchase our common stock, cash payments to support our development and discovery programs, including acquisition of in-process research and development technology, tax payments and operating cash payments for employee-related expenditures and restructuring.

Cash flow activities were as follows (dollars in thousands):

	Year Ended December 31,		Percent Change
	2024	2023	
Net cash provided by operating activities	$ 699,971	$ 333,324	110%
Net cash used in investing activities	$ (116,783)	$ (26,955)	333%
Net cash used in financing activities	$ (628,808)	$ (546,052)	15%

Operating Activities

Cash provided by operating activities is derived by adjusting our net income for non-cash operating items such as deferred taxes, stock-based compensation, depreciation and amortization, non-cash lease expense, impairment of long-lived assets, and changes in operating assets and liabilities, which reflect timing differences between the receipt and payment of cash associated with transactions and when they are recognized in our Consolidated Statements of Income.

Net cash provided by operating activities increased for the year ended December 31, 2024, as compared to 2023, primarily due to an increase in cash received on sales of our products, an increase in cash received upon achievement of milestones from Ipsen, and lower cash paid for operating expenses, partially offset by cash payments related to the 2024 Restructuring Plan.

Investing Activities

The changes in cash flows from investing activities primarily relates to the timing of marketable securities activity, acquisition of in-process research and development technology and capital expenditures. Our capital expenditures primarily consist of investments to expand our operations and acquire assets that further support our research and development activities.

Net cash used in investing activities increased for the year ended December 31, 2024, as compared to 2023. The increase in cash used in investing activities was primarily due to a decrease in cash proceeds from maturities and sales of

marketable securities and an increase in purchases of marketable securities, partially offset by a decrease in purchases of in-process research and development technology related to certain in-licensing collaboration arrangements and a decrease in purchases of property and equipment.

Financing Activities

The changes in cash flows from financing activities primarily relate to payments for repurchases of common stock, proceeds from employee stock programs and taxes paid related to net share settlement of equity awards.

Net cash used in financing activities increased for the year ended December 31, 2024, as compared to 2023. The increase in cash used in financing activities was primarily due to an increase in payments for repurchases of common stock.

Contractual Obligations

As of December 31, 2024, we anticipate the aggregate of our cash, cash equivalents and marketable securities and cash generated from operations to be sufficient to fund our contractual obligations, as well as cash requirements to support our ongoing operations and capital expenditures. Our contractual obligations as of December 31, 2024 primarily consist of:

Operating leases: We have certain lease agreements related to our corporate campus facilities and laboratory facilities located in Alameda, California and Greater Philadelphia area, under which we are obligated to make lease payments. As of December 31, 2024, we had $26.5 million of lease payments due in one year and $259.2 million due over the remaining lease term.

Purchase obligations: Purchase obligations include firm purchase commitments related to manufacturing of inventory, software services and other facilities and equipment. As of December 31, 2024, we had $63.4 million total purchase obligations due within one year and $13.3 million due after one year.

Contingent payments: We have committed to make certain contingent payments for potential future milestones, research funding commitments and royalties to certain collaboration partners, including contingent exercise fee payments if we decide to exercise certain of our options to in-license or acquire in-process research and development technology as part of our agreements with those parties. We do not expect these contingent payments to have a significant impact on our liquidity in the near term.

See “Notes 4. Collaboration Agreements and Business Development Activities” and “Note 12. Commitments and Contingencies” of the “Notes to Consolidated Financial Statements” in Part II, Item 8 of this Annual Report on Form 10-K for additional information regarding our contractual obligations and contingencies.

As of December 31, 2024, we did not have any material off-balance-sheet arrangements, as defined by applicable SEC regulations.

Critical Accounting Policies and Estimates

The preparation of our Consolidated Financial Statements conforms to accounting principles generally accepted in the U.S. which requires management to make judgments, estimates and assumptions that affect the reported amounts of assets, liabilities, equity, revenues and expenses, and related disclosures. An accounting policy is considered to be critical if it requires an accounting estimate to be made based on assumptions about matters that are highly uncertain at the time the estimate is made, and if different estimates that reasonably could have been used, or changes in the accounting estimates that are reasonably likely to occur periodically, could materially impact our Consolidated Financial Statements. On an ongoing basis, management evaluates its estimates including, but not limited to: those related to revenue recognition, including determining the nature and timing of satisfaction of performance obligations, and determining the standalone selling price of performance obligations, and variable consideration such as rebates, chargebacks, sales returns and sales allowances as well as milestones included in collaboration arrangements; the accrual for certain liabilities including accrued clinical trial liabilities; and valuations of equity awards used to determine stock-based compensation, including certain awards with vesting subject to market or performance conditions; and the amounts of deferred tax assets and liabilities including the related valuation allowance. We base our estimates on historical experience and on various other 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. Our senior management has discussed the development, selection and disclosure of these estimates with the Audit Committee of our Board of Directors. Actual results could differ materially from those estimates.

We believe our critical accounting policies relating to revenue recognition, clinical trial and collaboration accruals, stock-based compensation and income taxes reflect the more significant estimates and assumptions used in the preparation of our Consolidated Financial Statements.

For a complete description of our significant accounting policies, see "Note 1. Organization and Summary of Significant Accounting Policies" of the "Notes to Consolidated Financial Statements" in Part II, Item 8 of this Annual Report on Form 10-K.

Revenue Recognition

Net Product Revenues and Discounts and Allowances

We recognize revenues when our customers obtain control of promised goods or services, in an amount that reflects the consideration to which we are entitled to in exchange for those goods or services. We calculate gross product revenues based on the price that we charge to the specialty pharmacies and distributors in the U.S. We estimate our domestic net product revenues by deducting from our gross product revenues: (a) trade allowances, such as discounts for prompt payment; (b) estimated government rebates and chargebacks; (c) certain other fees paid to specialty pharmacies, distributors and commercial payors; and (d) returns. We record estimates for these deductions at the time we recognize the related gross product revenue. However, the actual rebate or chargeback on the sale of our product to a distributor is not invoiced to us until a future period, generally within three months from the date of sale. Due to this time lag, we must estimate the amount of rebates and chargebacks to accrue. We base our estimates for the expected utilization on customer and payer data received from the specialty pharmacies and distributors and historical utilization rates. We update our estimates every quarter to reflect actual claims and other current information. Actual rebates and chargebacks claimed for prior periods have varied from our estimates by less than 1% of the amount deducted from gross product revenues for the years ended December 31, 2024 and 2023. Our current estimates may differ significantly from actual results.

Collaboration Revenues

We enter into collaboration arrangements with third parties, under which we license certain rights to our intellectual property, and account for the arrangements as either license revenue or collaboration services revenue when the counterparty is a customer. The terms of these arrangements may include payments to us for one or more of the following: non-refundable, up-front license fees; development, regulatory and commercial milestone payments; product supply services; development cost reimbursements; profit sharing arrangements; and royalties on net sales of licensed products.

As part of the accounting for these arrangements, we must develop assumptions that require judgment to determine the standalone selling price for each performance obligation identified in the contract. We use key assumptions to determine the standalone selling price, which may include forecast revenues and costs, clinical development timelines and costs, reimbursement rates for personnel costs, discount rates and probabilities of technical and regulatory success. At the inception of each arrangement that includes development milestone payments, we evaluate whether the milestones are considered probable of being reached and estimate the amount to be included in the transaction price using the most likely amount method. At the end of each subsequent reporting period, we re-evaluate the probability of earning of such development milestones and any related constraint, and if necessary, adjust our estimate of the overall transaction price. For arrangements that may include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sale occurs or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). Development milestone adjustments are recorded on a cumulative catch-up basis, which would affect collaboration services revenues in the period of adjustment. In addition, in recording revenues for our research and development services performance obligations, we use projected development cost estimates to determine the amount of revenue to record as we satisfy this performance obligation.

Clinical Trial and Collaboration Accruals

We execute all of our clinical trials with support from contract research organizations and other vendors and we accrue costs for clinical trial activities performed by these third parties based upon the estimated amount of work completed on each trial. For clinical trial expenses, the significant factors used in estimating accruals include the number of patients enrolled, the activities performed for each patient, the number of active clinical sites and the duration for which the patients will be enrolled in the trial. Certain of our in-licensing collaboration arrangements include contingent payments in the form of development, regulatory and commercial milestones. We recognize expense for contingent payments when

they are deemed probable of achievement which requires judgment as to the probability and timing of the achievement of the underlying milestones. To the extent actual results, or updated probability estimates, differ from current estimates, such amounts are recorded as an adjustment in the period estimates are revised. We monitor patient enrollment levels and assess the related research and development activities progress, including the probability of achieving milestones payments associated to the respective terms and conditions of our in-licensing and collaboration arrangements to the extent possible through internal reviews and estimates of the operational progress of our discovery and early-stage clinical development programs, correspondence with contract research organizations and review of contractual terms. We base our estimates on the best information available at the time. However, additional information may become available to us, which may allow us to make a more accurate estimate in future periods. If we do not identify costs that we have begun to incur or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates.

Stock-based Compensation

Stock-based compensation expense requires us to estimate the fair value of performance-based restricted stock units (PSUs) and restricted stock units (RSUs) subject to market conditions, and estimate the number of shares subject to PSUs and RSUs with market conditions that will ultimately vest. To determine the fair value, we use models that require a number of complex and subjective assumptions including our stock price volatility, employee exercise patterns and risk-free interest rates. Monte Carlo simulation models are used to determine grant date fair value of awards with market conditions. The assumptions used in calculating the fair value of market conditions awards represent management's best estimates, but these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and we use different assumptions, our stock-based compensation expense could be materially different in the future.

We recognize stock-based compensation for PSUs over the requisite service period only for awards which we estimate will ultimately vest, which requires judgment as to the probability and timing of the achievement of the underlying performance goals. Significant factors we consider in making those judgments include forecasts of our product revenues and those of our collaboration partners, estimates regarding the operational progress of late-stage clinical development programs and discovery pipeline expansion performance targets. To the extent actual results, or updated estimates, differ from current estimates, such amounts are recorded as a cumulative adjustment in the period estimates are revised and as such, can materially affect our stock-based compensation expense in the current period and in the future. Compensation expense related to RSUs with market vesting conditions is recognized regardless of the outcome of the market conditions.

Income Taxes

We compute our income tax provision or benefit under the asset and liability method. Significant estimates are required in determining our income tax provision or benefit. We base some of these estimates on interpretations of existing tax laws or regulations. We recognize deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Under this method, deferred tax assets and liabilities are determined on the basis of the difference between the tax basis of assets and liabilities and their respective financial reporting amounts (temporary differences) at enacted tax rates in effect for the years in which the differences are expected to reverse. A valuation allowance is established for deferred tax assets for which it is more likely than not that some portion or all of the deferred tax assets, including net operating losses and tax credits, will not be realized. We periodically re-assess the need for a valuation allowance against our deferred tax assets based on various factors including our historical earnings experience by taxing jurisdiction, and forecasts of future operating results and utilization of net operating losses and tax credits prior to their expiration. Significant judgment is required in making this assessment and, to the extent that we deem a reversal of any portion of our valuation allowance against our deferred tax assets to be appropriate, we recognize a tax benefit against our income tax provision in the period of such reversal.

We recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained upon examination by tax authorities based on the technical merits of the position. The tax benefit recognized in the Consolidated Financial Statements for a particular tax position is based on the largest benefit that is more likely than not to be realized. The amount of unrecognized tax benefits is adjusted as appropriate for changes in facts and circumstances, such as significant amendments to existing tax law, new regulations or interpretations by tax authorities, new information obtained during a tax examination or resolution of an examination. We have elected to record interest and penalties in the accompanying Consolidated Statements of Income as a component of income taxes.

Recent Accounting Pronouncements

For a description of the expected impact of recent accounting pronouncements, see "Note 1. Organization and Summary of Significant Accounting Policies" of the "Notes to Consolidated Financial Statements" in Part II, Item 8 of this Annual Report on Form 10-K.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to cash flow and earnings fluctuations as a result of certain market risks. These market risks primarily relate to changes in interest rates and foreign exchange rates. Our investment portfolio is used to preserve our capital until it is required to fund operations, including our research and development activities. None of these market risk-sensitive instruments are held for trading purposes.

Interest Rate Risk

We invest our cash in a variety of financial instruments, principally securities issued by the U.S. government and its agencies, investment-grade corporate bonds and commercial paper, and money market funds. These investments are denominated in U.S. Dollars. All of our interest-bearing securities are subject to interest rate risk and could decline in value if interest rates fluctuate. Substantially all of our investment portfolio consists of marketable securities with active secondary or resale markets to help ensure portfolio liquidity, and we have implemented guidelines limiting the term-to-maturity of our investment instruments. Due to the conservative and short-term nature of these instruments, we do not believe that we have a material exposure to interest rate risk. If market interest rates were to increase or decrease by one percentage point, the fair value of our investment portfolio would increase or decrease by an immaterial amount.

Foreign Exchange Rate Risk

Fluctuations in the exchange rates of the U.S. dollar and foreign currencies may have the effect of increasing or decreasing our revenues and expenses and related financial assets, liabilities and cash flows. Royalty revenues and sales-based milestones we receive from our collaboration agreements with Ipsen, Takeda and Genentech are a percentage of the net sales made by those collaboration partners from sales made in countries outside the U.S. and are denominated in currencies in which the product is sold, which is predominantly the Euro or Japanese Yen. Research and development expenses include clinical trial and other services performed by third-party contract research organizations and other vendors located outside the U.S. that may bill us in currencies where their services are provided, which is predominantly the Euro. If the U.S. dollar strengthens against a foreign currency, then our royalty revenues will decrease for the same number of units sold in that foreign currency and the date we achieve certain sales-based milestones may also be delayed. Similarly, if the U.S. dollar weakens against a foreign currency, then our research and development expenses would increase. However, we believe that we are not subject to material risks arising from changes in foreign exchange rates and that a hypothetical 10% increase or decrease in foreign exchange rates would not have a material adverse impact on our financial condition, results of operations or cash flows. From time to time we have entered into forward foreign currency exchange contracts, that are not designated as hedges for accounting purposes, to hedge certain operational exposures for the changes in foreign currency exchange rates associated with assets or liabilities denominated in foreign currencies, primarily the Euro. Our strategy is to enter into foreign currency forward contracts for currencies in which we have an asset or liability exposure so that increases or decreases in the foreign currency exposure are offset by gains or losses on the foreign currency forward contracts, which mitigate the risks and volatility associated with certain foreign currency transactions. See "Note 6. Fair Value Measurements — Forward Foreign Currency Contracts" of the "Notes to Consolidated Financial Statements" in Part II, Item 8 of this Annual Report on Form 10-K for additional information about our foreign currency forward contracts.

Item 8. Financial Statements and Supplementary Data.

EXELIXIS, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Exelixis, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Exelixis, Inc. (the Company) as of January 3, 2025 and December 29, 2023, the related consolidated statements of income, comprehensive income, stockholders' equity and cash flows for each of the three years in the period ended January 3, 2025, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at January 3, 2025 and December 29, 2023, and the results of its operations and its cash flows for each of the three years in the period ended January 3, 2025, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of January 3, 2025, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 11, 2025 expressed an unqualified opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

	Net product revenue
Description of the Matter	For the year ended January 3, 2025, the Company recorded net product revenue of $1.8 billion. As discussed in Note 1 and Note 3 to the consolidated financial statements, the Company sells its products principally to specialty distributors and specialty pharmacy providers, or collectively, Customers. These Customers subsequently resell the products to health care providers and patients. Revenues from product sales are recognized net of accruals for estimated rebates, wholesaler chargebacks, discounts and other deductions (collectively discounts and allowances), which are estimated at the time of sale.

	Auditing the Company's net product revenue was complex and involved judgment given the volume of sales transactions and estimated rebates and chargebacks accruals related to U.S. product sales. Revenue from product sales is recognized upon transfer of control of a product to a customer, generally upon delivery, and is based on an amount that reflects the consideration to which the Company expects to be entitled, which represents an amount that is net of accruals for estimated discounts and allowances.
How We Addressed the Matter in Our Audit	We obtained an understanding, evaluated the design and tested the operating effectiveness of controls over the Company's revenue recognition process to determine the timing and measurement of product revenue and estimation of discounts and allowances. This included testing controls over management's review of key assumptions and inputs used in the estimation of discounts and allowances, including but not limited to products delivered, contractual terms, and historical experience. Our audit procedures over net product revenue included, among others, performing analytical procedures over revenues recognized and cash collections, testing appropriate cut-off of revenue recognition at period-end, and confirming a sample of outstanding receivable balances with customers. We also evaluated the Company's methodology used to estimate discounts and allowances, tested key assumptions, and assessed the historical accuracy of the Company's estimates of discounts and allowances by comparing assumptions to historical trends and evaluating the change from prior periods. We further tested the completeness and accuracy of the underlying data used in the Company's calculations through reconciliation to third-party invoices, claims data and actual cash payments.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2002.

San Mateo, California
February 11, 2025

EXELIXIS, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except per share data)

	December 31,	
	2024	**2023**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 217,374	$ 262,994
Marketable securities	893,902	732,308
Trade receivables, net	265,437	237,407
Inventory	22,388	17,323
Prepaid expenses and other current assets	68,478	67,926
Total current assets	1,467,579	1,317,958
Non-current marketable securities	637,291	728,717
Property and equipment, net	119,391	128,731
Deferred tax assets, net	420,027	361,145
Goodwill	63,684	63,684
Right-of-use assets and other non-current assets	239,718	342,122
Total assets	$ 2,947,690	$ 2,942,357
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 38,191	$ 33,768
Accrued compensation and benefits	109,830	93,325
Accrued clinical trial liabilities	57,976	71,615
Rebates and fees due to customers	62,376	59,619
Accrued collaboration liabilities	40,384	27,533
Other current liabilities	95,012	108,417
Total current liabilities	403,769	394,277
Non-current operating lease liabilities	190,823	189,944
Other non-current liabilities	108,895	94,224
Total liabilities	703,487	678,445
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000 shares authorized and no shares issued	—	—
Common stock, $0.001 par value; 400,000 shares authorized; issued and outstanding: 281,732 and 302,793 at December 31, 2024 and 2023, respectively	282	303
Additional paid-in-capital	2,343,915	2,440,710
Accumulated other comprehensive loss	(1,347)	(3,750)
Accumulated deficit	(98,647)	(173,351)
Total stockholders' equity	2,244,203	2,263,912
Total liabilities and stockholders' equity	$ 2,947,690	$ 2,942,357

The accompanying notes are an integral part of these Consolidated Financial Statements.

EXELIXIS, INC.
CONSOLIDATED STATEMENTS OF INCOME
(in thousands, except per share data)

	Year Ended December 31,		
	2024	**2023**	**2022**
Revenues:			
Net product revenues	$ 1,809,395	$ 1,628,879	$ 1,401,243
License revenues	349,244	178,635	162,056
Collaboration services revenues	10,062	22,694	47,763
Total revenues	2,168,701	1,830,208	1,611,062
Operating expenses:			
Cost of goods sold	76,216	72,547	57,909
Research and development	910,408	1,044,071	891,813
Selling, general and administrative	492,128	542,705	459,856
Impairment of long-lived assets	51,672	—	—
Restructuring	33,660	—	—
Total operating expenses	1,564,084	1,659,323	1,409,578
Income from operations	604,617	170,885	201,484
Interest income	77,156	86,543	33,065
Other income (expense), net	(133)	93	(197)
Income before income taxes	681,640	257,521	234,352
Provision for income taxes	160,373	49,756	52,070
Net income	$ 521,267	$ 207,765	$ 182,282
Net income per share:			
Basic	$ 1.80	$ 0.65	$ 0.57
Diluted	$ 1.76	$ 0.65	$ 0.56
Weighted-average common shares outstanding:			
Basic	290,030	318,151	321,526
Diluted	296,132	321,464	324,556

The accompanying notes are an integral part of these Consolidated Financial Statements.

EXELIXIS, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(in thousands)

	Year Ended December 31,		
	2024	**2023**	**2022**
Net income	$ 521,267	$ 207,765	$ 182,282
Other comprehensive income (loss):			
Net unrealized gains (losses) on available-for-sale debt securities, net of tax impact of $(706), $(3,174) and $3,886, respectively	2,403	10,771	(13,763)
Comprehensive income	$ 523,670	$ 218,536	$ 168,519

The accompanying notes are an integral part of these Consolidated Financial Statements.

EXELIXIS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2021	318,842	$ 319	$ 2,427,561	$ (758)	$ (216,507)	$ 2,210,615
Net income	—	—	—	—	182,282	182,282
Other comprehensive loss	—	—	—	(13,763)	—	(13,763)
Issuance of common stock under the equity incentive plan and stock purchase plan	5,109	5	23,976	—	—	23,981
Stock transactions associated with taxes withheld on equity awards	—	—	(23,344)	—	—	(23,344)
Stock-based compensation	—	—	108,656	—	—	108,656
Balance at December 31, 2022	323,951	324	2,536,849	(14,521)	(34,225)	2,488,427
Net income	—	—	—	—	207,765	207,765
Other comprehensive income	—	—	—	10,771	—	10,771
Issuance of common stock under the equity incentive plan and stock purchase plan	5,072	5	33,489	—	—	33,494
Stock transactions associated with taxes withheld on equity awards	—	—	(29,083)	—	—	(29,083)
Repurchase of common stock	(26,230)	(26)	(207,953)	—	(346,891)	(554,870)
Stock-based compensation	—	—	107,408	—	—	107,408
Balance at December 31, 2023	302,793	303	2,440,710	(3,750)	(173,351)	2,263,912
Net income	—	—	—	—	521,267	521,267
Other comprehensive income	—	—	—	2,403	—	2,403
Issuance of common stock under the equity incentive plan and stock purchase plan	5,356	5	61,775	—	—	61,780
Stock transactions associated with taxes withheld on equity awards	—	—	(38,632)	—	—	(38,632)
Repurchases of common stock	(26,417)	(26)	(214,640)	—	(446,563)	(661,229)
Stock-based compensation	—	—	94,702	—	—	94,702
Balance at December 31, 2024	281,732	$ 282	$ 2,343,915	$ (1,347)	$ (98,647)	$ 2,244,203

The accompanying notes are an integral part of these Consolidated Financial Statements.

EXELIXIS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,		
	2024	2023	2022
Net income	$ 521,267	$ 207,765	$ 182,282
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	28,803	25,717	20,875
Impairment of long-lived assets	64,391	—	—
Stock-based compensation	93,836	106,345	107,574
Non-cash lease expense	27,461	28,976	18,315
Deferred taxes	(59,458)	(133,209)	(60,358)
Acquired in-process research and development technology	50,750	128,500	107,250
Other, net	(13,626)	(16,797)	(525)
Changes in operating assets and liabilities:			
Trade receivable, net	(27,950)	(22,623)	66,849
Inventory	5,453	(12,977)	(11,683)
Prepaid expenses and other assets	31,079	(29,824)	(28,259)
Accrued collaboration liabilities	(149)	1,345	(63,065)
Accounts payable and other liabilities	(21,886)	50,106	23,359
Net cash provided by operating activities	699,971	333,324	362,614
Cash flows from investing activities:			
Purchases of marketable securities	(927,905)	(902,468)	(1,450,716)
Proceeds from maturities and sales of marketable securities	877,307	1,038,482	1,064,758
Purchases of property, equipment and other, net	(28,435)	(40,469)	(27,706)
Acquired in-process research and development technology	(37,750)	(122,500)	(110,750)
Net cash used in investing activities	(116,783)	(26,955)	(524,414)
Cash flows from financing activities:			
Payments for repurchases of common stock	(652,033)	(550,378)	—
Proceeds from issuance of common stock under the equity incentive plan and stock purchase plan	61,850	33,448	23,886
Taxes paid related to net share settlement of equity awards	(38,625)	(29,122)	(23,300)
Net cash provided by (used in) financing activities	(628,808)	(546,052)	586
Net decrease in cash and cash equivalents	(45,620)	(239,683)	(161,214)
Cash and cash equivalents at beginning of period	262,994	502,677	663,891
Cash and cash equivalents at end of period	$ 217,374	$ 262,994	$ 502,677
Supplemental cash flow disclosures:			
Cash paid for taxes	$ 170,482	$ 185,658	$ 127,870
Non-cash operating activities:			
Right-of-use assets obtained in exchange for lease obligations	$ 15,313	$ 16,623	$ 155,935
Impairment of right-of-use assets	$ 59,735	$ —	$ —
Non-cash investing activity:			
Unpaid liabilities incurred for purchases of in-process research and development technology	$ 19,500	$ 6,500	$ 500

The accompanying notes are an integral part of these Consolidated Financial Statements.

NOTE 1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Organization

Exelixis, Inc. (Exelixis, we, our or us) is an oncology company innovating next-generation medicines and combination regimens at the forefront of cancer care. We have produced four marketed pharmaceutical products, two of which are formulations of our flagship molecule, cabozantinib, and we are steadily advancing and evolving our product pipeline portfolio, including our lead asset zanzalintinib, currently the focus of an extensive phase 3 clinical development program. With a rational and disciplined approach to investment, we are leveraging our internal experience and expertise, and the strength of strategic partnerships, to identify and pursue opportunities across the landscape of scientific modalities, including small molecules, biotherapeutics and antibody-drug conjugates (ADCs).

Sales related to cabozantinib account for the majority of our revenues. Cabozantinib is an inhibitor of multiple tyrosine kinases, including MET, AXL, VEGF receptors and RET and has been approved by the U.S. Food and Drug Administration (FDA) and in other countries: as CABOMETYX® (cabozantinib) tablets for advanced renal cell carcinoma (RCC) (both alone and in combination with Bristol-Myers Squibb Company's (BMS) nivolumab), for previously treated hepatocellular carcinoma (HCC) and for previously treated, radioactive iodine (RAI)-refractory differentiated thyroid cancer (DTC); and as COMETRIQ® (cabozantinib) capsules for progressive, metastatic medullary thyroid cancer. For physicians treating these types of cancer, cabozantinib has become or is becoming an important medicine in their selection of effective therapies.

The other two products resulting from our discovery efforts are: COTELLIC® (cobimetinib), an inhibitor of MEK approved as part of multiple combination regimens to treat specific forms of advanced melanoma and marketed under a collaboration with Genentech, Inc. (a member of the Roche Group) (Genentech); and MINNEBRO® (esaxerenone), an oral, non-steroidal, selective blocker of the mineralocorticoid receptor, approved for the treatment of hypertension in Japan and licensed to Daiichi Sankyo Company, Limited (Daiichi Sankyo).

Basis of Presentation

The accompanying Consolidated Financial Statements include the accounts of Exelixis and those of our wholly-owned subsidiaries. These entities' functional currency is the U.S. dollar. All intercompany balances and transactions have been eliminated.

We have adopted a 52- or 53-week fiscal year policy that generally ends on the Friday closest to December 31st. Fiscal year 2024, which was a 53-week fiscal year, ended on January 3, 2025; fiscal year 2023, which was a 52-week fiscal year, ended on December 29, 2023; and fiscal year 2022, which was a 52-week fiscal year, ended on December 30, 2022. For convenience, references in this report as of and for the fiscal years ended January 3, 2025, December 29, 2023 and December 30, 2022, are indicated as being as of and for the years ended December 31, 2024, 2023 and 2022, respectively.

We have made reclassifications to our prior years' Consolidated Financial Statements to conform to the current year's presentation. These reclassifications did not impact previously reported total revenues, income from operations, net income, total assets, total liabilities, total operating, investing or financing cash flows or total stockholders' equity.

Use of Estimates

The preparation of the accompanying Consolidated Financial Statements conforms to accounting principles generally accepted in the U.S., which requires management to make judgments, estimates and assumptions that affect the reported amounts of assets, liabilities, equity, revenues and expenses and related disclosures. On an ongoing basis, we evaluate our significant estimates. We base our estimates on historical experience and on various other 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. Actual results could differ materially from those estimates.

Recently Adopted Accounting Pronouncements

In November 2023, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, which enhances the disclosures required for operating segments in our annual and interim consolidated financial statements. We adopted the new standard effective beginning fiscal year 2024. We have presented the effects of the adoption of ASU 2023-07 in "Note 2. Segment Reporting."

Cash, Cash Equivalents and Marketable Securities

We consider all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. Cash equivalents include high-grade, short-term investments in money market funds and marketable debt securities which are subject to minimal credit and market risk.

We designate all investments in marketable debt securities and certificates of deposit as available-for-sale and therefore, report such investments at fair value, with unrealized gains and losses recorded in accumulated other comprehensive income. For securities sold prior to maturity, the cost of securities sold is based on the specific identification method. We include realized gains and losses on the sale of marketable securities in other income (expense), net in the accompanying Consolidated Statements of Income.

We classify those marketable securities that we do not require for use in current operations and that mature in more than 12 months as non-current marketable securities in the accompanying Consolidated Balance Sheets.

Investment Impairment

Quarterly, we assess each of our investments in available-for-sale debt securities whose fair value is below its cost basis to determine if the investment's impairment is due to credit-related factors or noncredit-related factors. Factors considered in determining whether an impairment is credit-related include the extent to which the investment's fair value is less than its cost basis, declines in published credit ratings, issuer default on interest or principal payments, and declines in the financial condition and near-term prospects of the issuer. If we determine a credit-related impairment exists, we will measure the credit loss based on a discounted cash flow model. Credit-related impairments on available-for-sale debt securities are recognized as an allowance for credit losses with a corresponding adjustment to other income (expense), net in the accompanying Consolidated Statements of Income. The portion of the impairment that is not credit-related is recorded as a reduction of other comprehensive income (loss), net of applicable taxes.

We have elected to exclude accrued interest from both the fair value and the amortized cost basis of the available-for-sale debt securities for the purposes of identifying and measuring an impairment. We write-off accrued interest as a reduction of interest income when an issuer has defaulted on interest payments due on a security.

Fair Value Measurements

Fair value is defined as the amount that would be received upon sale of an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date (exit price). When determining the fair value measurements for assets and liabilities which are required to be recorded at fair value, we consider the principal or most advantageous market in which we would transact and the market-based risk measurements or assumptions that market participants would use in pricing the asset or liability, such as risks inherent in valuation techniques, transfer restrictions and credit risks.

Foreign Currency Remeasurement

Monetary assets and liabilities denominated in currencies other than the functional currency are remeasured using exchange rates in effect at the end of the period and related gains or losses are recorded in other income (expense), net in the accompanying Consolidated Statements of Income. Net foreign currency gains or losses were immaterial for the years ended December 31, 2024, 2023 and 2022, respectively.

Accounts Receivable

Trade receivables, net, contain amounts billed to our customers for product sales, and amounts billed to our collaboration partners for development, regulatory and sales-based milestone payments, royalties on the sale of licensed products, profit-sharing arrangements, development cost reimbursements, and payments for product supply services. Our

customers are primarily pharmaceutical and biotechnology companies that are located in the U.S., and collaboration partners that are located in Europe and Japan. We record trade receivables net of allowances for credit losses and chargebacks, and cash discounts for prompt payment. We apply an aging method to estimate credit losses and consider our historical loss information, adjusted to account for current economic conditions, and reasonable and supportable forecasts of future economic conditions affecting our customers. We write off trade receivables and related allowances for credit losses when it becomes probable we will not collect the amount receivable. The allowances for credit losses and write-offs for the years ended December 31, 2024 and December 31, 2023 were immaterial.

Inventory

We value inventory at the lower of cost or net realizable value. We determine the cost of inventory using the standard-cost method, which approximates actual cost based on a first-in, first-out method. We analyze our inventory levels quarterly and write down inventory subject to expiry in excess of expected requirements, or that has a cost basis in excess of its expected net realizable value. These write downs are charged to either cost of goods sold or the cost of supplied product included in collaboration services revenues in the accompanying Consolidated Statements of Income. On a quarterly basis, we analyze our estimated production levels for the following twelve-month period, which is our normal operating cycle, and reclassify inventory we expect to use or sell in periods beyond the next twelve months into other long-term assets in the accompanying Consolidated Balance Sheets.

Property and Equipment

We record property and equipment at cost, net of depreciation. We compute depreciation using the straight-line method based on estimated useful lives of the assets and amortize leasehold improvements over the lesser of their estimated useful lives or the remainder of the lease term. We charge repairs and maintenance costs to expense as incurred. We periodically review property and equipment for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable.

Long-Lived Assets Impairment

The carrying value of our long-lived assets, which includes property and equipment, right-of-use assets and leasehold improvements, is reviewed for impairment whenever events or changes in circumstances indicate that the carrying value of the asset may not be recoverable. Should there be an indication of impairment, we test for recoverability by comparing the estimated undiscounted future cash flows expected to result from the use of the asset to the carrying amount of the asset or asset group. If the asset or asset group is determined to be impaired, any excess of the carrying value of the asset or asset group over its estimated fair value is recognized as an impairment loss. The fair value is determined using an income approach where certain Level 3 inputs are used, including estimates and assumptions on the timing and amount of discounted cash flows. During the year ended December 31, 2024, we recognized $64.4 million in impairment charges primarily comprised of right-of use assets, leasehold improvements, and property and equipment. We did not recognize any material impairment charges during the years ended December 31, 2023 and 2022. See “Note 12. Commitments and Contingencies – *Impairment of long-lived assets*” and “Note 13. Restructuring” for further details.

Leases

We determine if an arrangement includes a lease at the inception of the agreement. For each of our lease arrangements, we record a right-of-use asset representing our right to use an underlying asset for the lease term and a lease liability representing our obligation to make lease payments. Operating lease right-of-use assets and liabilities are recognized at the lease commencement date based on the net present value of lease payments over the lease term. In determining the discount rate used to calculate the net present value of lease payments, we use our incremental borrowing rate based on the information available at the lease commencement date. Our leases may include options to extend or terminate the lease which are included in the lease term when it is reasonably certain that we will exercise any such options. The Company elected to account for lease and non-lease components as a single lease component. Lease expense for our operating leases is recognized on a straight-line basis over the lease term. Impairments of right-of-use assets are recognized as a reduction in their respective carrying values. Post-impairment, the lease expense for our operating leases is comprised of the straight-line amortization of the remaining right-of-use assets over the lease term and the accretion of lease liability. We have elected not to apply the recognition requirements of Topic 842, *Leases,* for short-term leases that do not include an option to purchase the underlying asset for which the Company is reasonably certain to exercise. For short-term leases, lease payments are recognized as incurred in operating expenses over the lease term.

Goodwill

We record goodwill amounts as the excess of purchase price over identifiable net assets acquired based on their estimated fair value. We review the carrying amount of goodwill for impairment annually and whenever events or changes in circumstance indicate that the carrying value may not be recoverable. We perform our annual assessment of the recoverability of our goodwill as of the first day of our fourth quarter. The assessment of recoverability may first consider qualitative factors to determine whether the existence of events or circumstances leads to a determination that it is more-likely-than-not that the fair value of a reporting unit is less than its carrying amount. We perform a quantitative assessment if the qualitative assessment results in a more-likely-than-not determination or if a qualitative assessment is not performed. The quantitative assessment considers whether the carrying amount of a reporting unit exceeds its fair value, in which case an impairment charge is recorded for the amount by which the carrying amount of a reporting unit exceeds its fair value, limited to the goodwill balance. We operate in one business segment, which is also considered to be our sole reporting unit and therefore, goodwill is tested for impairment at the enterprise level. We did not recognize any goodwill impairment charges in any of the periods presented.

Other current liabilities

As of December 31, 2024 and 2023, other current liabilities includes the current portion of the Branded Prescription Drug Fee due to the Internal Revenue Service in the amount of $26.2 million and $26.3 million, respectively, and the current portion of our lease liability in the amount of $25.0 million and $25.7 million, respectively.

Revenue

We account for revenues under the guidance of Topic 606, *Revenues from Contracts with Customers* (Topic 606). Under Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration to which the entity is entitled to in exchange for those goods or services. To determine revenue recognition for arrangements that are within the scope of Topic 606, we perform the following five steps: (1) identify the contract(s) with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when (or as) we satisfy a performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer.

Net Product Revenues

We sell our products principally to specialty distributors and specialty pharmacy providers, or collectively, our Customers. These Customers subsequently resell our products to health care providers and patients. In addition to distribution agreements with Customers, we enter into arrangements with health care providers and payors that provide for government-mandated and/or privately-negotiated rebates, chargebacks and discounts with respect to the purchase of our products. Revenues from product sales are recognized when the Customer obtains control of our product, which occurs at a point in time, typically upon delivery to the Customer.

Product Sales Discounts and Allowances

We record revenues from product sales at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established primarily from chargebacks, discounts for prompt payment, rebates, co-pay assistance and other customer credits that are offered within contracts between us and our Customers, health care providers, payors and other indirect customers relating to the sales of our products. These reserves are based on the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if the amount is payable to the Customer) or a current liability (if the amount is payable to a party other than a Customer). Where appropriate, these estimates take into consideration a range of possible outcomes for relevant factors such as our historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted Customer buying and payment patterns. Overall, these reserves reflect our best estimates of the amount of consideration to which we are entitled based on the terms of our contracts. The amount of variable consideration that is included in the transaction price may be constrained, and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from our estimates, we will adjust these estimates, which would affect net product revenues and earnings in the period such variances become known.

Chargebacks: Chargebacks are discounts that occur when contracted Customers purchase directly from a specialty distributor. Contracted Customers, which currently consist primarily of Public Health Service institutions, Federal government entities purchasing via the Federal Supply Schedule, Group Purchasing Organizations, and health maintenance organizations, generally purchase the product at a discounted price. The specialty distributor, in turn, charges back to us the difference between the price initially paid by the specialty distributor and the discounted price paid to the specialty distributor by the Customer. The allowance for chargebacks is based on actual chargebacks received and an estimate of sales to contracted Customers.

Discounts for Prompt Payment: Our Customers in the U.S. receive a discount of 2% for prompt payment. We expect our Customers will earn 100% of their prompt payment discounts and, therefore, we deduct the full amount of these discounts from total product sales when revenues are recognized.

Rebates: Allowances for rebates consist primarily of mandated discounts under the Medicaid Drug Rebate Program, other government programs and commercial contracts. Rebate amounts owed after the final dispensing of the product to a benefit plan participant are based upon contractual agreements or legal requirements with public sector benefit providers, such as Medicaid. The allowance for rebates is based on statutory or contractual discount rates and expected utilization. Our estimates for the expected utilization of rebates are based on Customer and payer data received from the specialty pharmacies and distributors and historical utilization rates. Rebates are generally invoiced by the payer and paid in arrears, such that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's shipments to our Customers, plus an accrual balance for known prior quarters' unpaid rebates. If actual future rebates vary from estimates, we may need to adjust our accruals, which would affect net product revenues in the period of adjustment.

Allowances for rebates also include amounts related to the Medicare Part D Coverage Gap Discount and Manufacturer Discount programs. Our estimates for expected Medicare Part D coverage gap amounts are based on Customer and payer data received from specialty pharmacies and distributors and historical utilization rates. The coverage gap is invoiced and paid in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's shipments to Customers, plus an accrual balance for prior quarters' unpaid claims. If invoiced amounts vary from estimates, we may need to adjust our accruals, which would affect net product revenues in the period of adjustment.

Co-payment Assistance: Patients who have commercial insurance and meet certain eligibility requirements may receive co-payment assistance. We accrue a liability for co-payment assistance based on actual program participation and estimates of program redemption using Customer data provided by the specialty distributor that administers the copay program.

Other Customer Credits: We pay fees to our Customers for account management, data management and other administrative services. To the extent the services received are distinct from the sale of products to the Customer, we classify these payments in selling, general and administrative expenses in our Consolidated Statements of Income.

Collaboration Revenues

We assess whether our collaboration agreements are subject to Topic 808, *Collaborative Arrangements* (Topic 808), based on whether they involve joint operating activities and whether both parties have active participation in the arrangement and are exposed to significant risks and rewards. To the extent that the arrangement falls within the scope of Topic 808, we apply by analogy the unit of account guidance under Topic 606 to identify distinct performance obligations, and then determine whether a customer relationship exists for each distinct performance obligation. If we determine a performance obligation within the arrangement is with a customer, we apply the guidance in Topic 606. If a portion of a distinct bundle of goods or services within an arrangement is not with a customer, then the unit of account is not within the scope of Topic 606, and the recognition and measurement of that unit of account shall be based on analogy to authoritative accounting literature or, if there is no appropriate analogy, a reasonable, rational, and consistently applied accounting policy election.

We enter into collaboration arrangements, under which we license certain rights to our intellectual property to third parties. The terms of these arrangements may include payments to us for one or more of the following: nonrefundable up-front license fees; development, regulatory and sales-based milestone payments; product supply services; development cost reimbursements; profit-sharing arrangements; and royalties on net sales of licensed products. As part of the accounting for these arrangements, we develop assumptions that require judgment to determine the standalone selling price for each performance obligation identified in the contract. These key assumptions may include

forecasted revenues, clinical development timelines and costs, reimbursement rates for personnel costs, discount rates and probabilities of technical and regulatory success.

Up-front License Fees: If the license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenues from nonrefundable up-front fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license, which generally occurs at or near the inception of the contract. For licenses that are bundled with other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenues from nonrefundable up-front fees. We evaluate the measure of progress at the end of each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

Regulatory and Development Milestone Payments: At the inception of each arrangement that includes development milestone payments, we evaluate whether the milestones are considered probable of being reached and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our or the licensee's control, such as regulatory approvals, are not considered probable of being achieved until uncertainty associated with the approvals has been resolved. The transaction price is then allocated to each performance obligation, on a relative standalone selling price basis, for which we recognize revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, we re-evaluate the probability of achieving such development and regulatory milestones and any related variable consideration constraint, and if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis.

Product Supply Services: Arrangements that include a promise for the future supply of drug product for either clinical development or commercial supply at the licensee's discretion are generally considered as options. We assess if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations.

Development Cost Reimbursements: Our collaboration arrangements may include promises of future clinical development and drug safety services, as well as participation on certain joint committees. When such services are provided to a customer, and they are distinct from the licenses provided to our collaboration partners, these promises are accounted for as a separate performance obligation, which we estimate using internal development costs incurred and projections through the term of the arrangements. We record revenues for these services as the performance obligations are satisfied over time based on measure of progress. However, if we conclude that our collaboration partner is not a customer for those collaborative research and development activities, we present such payments as a reduction of research and development expenses.

Profit-sharing Arrangements: Under the terms of our collaboration agreement with Genentech for cobimetinib, we are entitled to a share of U.S. profits and losses received in connection with the commercialization of cobimetinib. We account for this arrangement in accordance with Topic 606. We have determined that we are an agent under the agreement and therefore revenues are recorded net of costs incurred. We record revenues for the variable consideration associated with the profits and losses under the collaboration agreement when it is probable that a significant reversal in the amount of cumulative revenues recognized will not occur.

Royalty and Sales-based Milestone Payments: For arrangements that include royalties and sales-based milestone payments, including milestone payments earned for the first commercial sale of a product, the license is deemed to be the predominant item to which such payments relate and we recognize revenues at the later of when the related sales occur or when the performance obligation to which the royalty has been allocated has been satisfied.

Cost of Goods Sold

Cost of goods sold is related to our product revenues and consists primarily of a 3% royalty we are required to pay on all net sales of any product containing cabozantinib, the cost of manufacturing, indirect labor costs, write-downs related to expiring and excess inventory, shipping and other third-party logistics and distribution costs for our product.

We consider regulatory approval of product candidates to be uncertain and product manufactured prior to regulatory approval may not be sold unless regulatory approval is obtained. As such, the manufacturing costs for product candidates incurred prior to regulatory approval are not capitalized as inventory but are expensed as research and development costs.

Research and Development Expenses

Research and development expenses consist of (1) direct and indirect internal costs for drug discovery; (2) upfront license and project initiation fees, license option fees and option exercise fees, funded research and milestone payments incurred or probable to be incurred for our in-licensing arrangements with our collaboration partners for research programs in development and prior to regulatory approval; and (3) development costs associated with our clinical trial projects, which include fees paid to Contract Research Organizations (CRO) performing work on our behalf.

Our clinical trial projects have been executed with support from third-party CROs, who specialize in conducting and managing global clinical trials. We accrue expenses for clinical trial activities performed by the CROs based upon the estimated amount of work completed on each trial. For clinical trial expenses, the significant factors used in estimating accruals include direct CRO costs, the number of patients enrolled, the number of active clinical sites involved, the duration for which the patients will be enrolled in the trial and patient out of pocket costs. We monitor patient enrollment levels and related activities to the extent possible through CRO meetings and correspondence, internal reviews and review of contractual terms. We base our estimates on the best information available at the time. However, additional information may become available to us which may allow us to make a more accurate estimate in future periods. In this event, we may be required to record adjustments to research and development expenses in future periods when the actual level of activity becomes more certain. As described further above, certain payments made to us from our collaboration partners may be presented as a reduction of research and development expense.

Advertising

Advertising expenses were $43.5 million, $40.0 million and $41.6 million for the years ended December 31, 2024, 2023 and 2022, respectively. We expense the costs of advertising, including promotional expenses, as incurred. Advertising expenses are recorded in selling, general and administrative expenses in the accompanying Consolidated Statements of Income.

Stock-Based Compensation

We account for stock-based payments to employees, including grants of service-based restricted stock units (RSUs), performance-based restricted stock units (PSUs), service-based stock options and purchases under our 2000 Employee Stock Purchase Plan (as amended and restated, the Amended ESPP) in accordance with Topic 718, *Compensation-Stock Compensation*, which requires that stock-based payments (to the extent they are compensatory) be recognized in our Consolidated Statements of Income based on their fair values. We account for forfeitures of stock-based awards as they occur. The expense for stock-based compensation is based on the grant date fair value of the award. The grant date fair value of RSUs and PSUs are estimated as the value of the underlying shares of our common stock. The grant date fair values for certain PSUs and RSUs with market vesting conditions are estimated using a Monte Carlo simulation pricing model and for stock options, using a Black-Scholes Merton option pricing model. Both pricing models require the input of subjective assumptions. These variables include, but are not limited to, the expected volatility of our stock price and the expected term of the awards. We consider both implied and historical volatility when developing an estimate of expected volatility. We estimate the term using historical data. We recognize compensation expense over the requisite service period on an accelerated basis for awards with a market or performance condition and on a straight-line basis for service-based stock options and awards. Compensation expense related to PSUs is recognized when we determine that it is probable that the performance goals will be achieved, which we assess on a quarterly basis. Compensation expense related to RSUs with market vesting conditions is recognized regardless of the outcome of the market conditions.

Provision for Income Taxes

Our provision for income taxes is computed under the asset and liability method. Significant estimates are required in determining our provision for income taxes. Some of these estimates are based on interpretations of existing tax laws or regulations. We recognize deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Under this method, deferred tax assets and liabilities are determined on the basis of the difference between the tax basis of assets and liabilities and their respective financial reporting amounts (temporary differences) at enacted tax rates in effect for the years in which the differences are expected to reverse. A valuation allowance is established for deferred tax assets for which it is more likely than not that some portion or all of the deferred tax assets, including net operating losses and tax credits, will not be realized. We periodically re-assess the need for a valuation allowance against our deferred tax assets based on various factors including our historical earnings experience by taxing jurisdiction, and forecasts of future operating results and utilization of net operating losses and tax credits prior to their expiration. Significant judgment is required in making this assessment and, to the extent that a reversal

of any portion of our valuation allowance against our deferred tax assets is deemed appropriate, a tax benefit will be recognized against our provision for income taxes in the period of such reversal. Based on our evaluation and weighing of both positive and negative evidence, including our achievement of a cumulative three-year income position as of December 31, 2024 and forecasts of future operating results, as well as considering the utilization of net operating losses and tax credits prior to their expiration, management has continued to determine that there is sufficient positive evidence to conclude that it is more likely than not the deferred tax assets are realizable and therefore, we do not have a valuation allowance against our deferred tax assets as described in "Note 10. Provision For Income Taxes", below. We continue to maintain a valuation allowance against our California state deferred tax assets and federal and state capital loss carryforwards.

We recognize tax benefits from uncertain tax positions only if it is more likely than not that the tax position will be sustained upon examination by the tax authorities based on the technical merits of the position. An adverse resolution of one or more of these uncertain tax positions in any period could have a material impact on the results of operations for that period.

Recent Accounting Pronouncements Not Yet Adopted

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* (ASU 2023-09), which enhances the disclosures required for income taxes in our annual consolidated financial statements. ASU 2023-09 is effective for us in our annual reporting for fiscal 2025 on a prospective basis. Early adoption and retrospective reporting are permitted. We are currently evaluating the impact of ASU 2023-09 on our Consolidated Financial Statements.

In November 2024, the FASB issued ASU 2024-03, *Income Statement – Reporting Comprehensive Income – Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses* (ASU 2024-03), which enhances the disclosures required for expense disaggregation in our annual and interim consolidated financial statements. ASU 2024-03 is effective for us in our annual reporting beginning in fiscal year 2027, and in our interim periods beginning in fiscal year 2028 on a prospective basis. Early adoption and retrospective application are permitted. We are currently evaluating the impact of ASU 2024-03 on our Consolidated Financial Statements.

NOTE 2. SEGMENT REPORTING

We operate in one business segment that focuses on the discovery, development and commercialization of new medicines for difficult-to-treat cancers. Our President and Chief Executive Officer, as the chief operating decision-maker, manages and allocates resources to our operations on a total consolidated basis. Consistent with this decision-making process, our President and Chief Executive Officer uses net income to monitor budget versus actual results for purposes of evaluating performance and to make decisions about the allocation of resources.

Our significant segment expenses are regularly provided to our President and Chief Executive Officer and included in the measure of segment net income of consolidated expenses for our operational departments consisting of drug discovery, development, and selling, general and administrative and other segment items.

Summary of the segment net income, including significant segment expenses were as follows (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Revenues	$ 2,168,701	$ 1,830,208	$ 1,611,062
Less:			
Cost of goods sold	76,216	72,547	57,909
Drug discovery	94,842	215,085	249,713
Development	665,847	669,240	521,622
Selling, general, and administrative	428,962	470,680	397,632
Other segment items[(1)]	298,350	231,678	182,899
Interest income	(77,156)	(86,543)	(33,065)
Provision for income taxes	160,373	49,756	52,070
Segment and consolidated net income	$ 521,267	$ 207,765	$ 182,282

[(1)] Other segment items include stock-based compensation expenses, restructuring expenses, impairment of long-lived assets, other research and development expenses including the allocation of general corporate costs to research and development services and development cost reimbursements in connection with certain of our collaboration arrangements, and other income (expenses), net.

All of our long-lived assets are located in the U.S. See “Note 3. Revenues” for enterprise-wide disclosures about product sales, revenues from major customers and revenues by geographic region.

NOTE 3. REVENUES

Revenues consisted of the following (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Product revenues:			
Gross product revenues	$ 2,518,246	$ 2,272,533	$ 1,951,169
Discounts and allowances	(708,851)	(643,654)	(549,926)
Net product revenues	1,809,395	1,628,879	1,401,243
Collaboration revenues:			
License revenues	349,244	178,635	162,056
Collaboration services revenues	10,062	22,694	47,763
Total collaboration revenues	359,306	201,329	209,819
Total revenues	$ 2,168,701	$ 1,830,208	$ 1,611,062

Net product revenues and license revenues are recorded in accordance with Accounting Standards Codification (ASC) Topic 606, *Revenue from Contracts with Customers* (Topic 606). License revenues include the recognition of the portion of milestone payments allocated to the transfer of intellectual property licenses for which it had become probable in the current period that the milestone would be achieved and a significant reversal of revenues would not occur, as well as royalty revenues and our share of profits under our collaboration agreement with Genentech. Collaboration services revenues are recorded in accordance with ASC Topic 808, *Collaborative Arrangements.* Collaboration services revenues include the recognition of deferred revenues for the portion of upfront and milestone payments allocated to our research and development services performance obligations, development cost reimbursements earned under our collaboration agreements, product supply revenues, net of product supply costs and the royalties we paid on sales of products containing cabozantinib by our collaboration partners.

Net product revenues by product were as follows (in thousands):

	Year Ended December 31,		
	2024	2023	2022
CABOMETYX	$ 1,798,237	$ 1,614,942	$ 1,375,909
COMETRIQ	11,158	13,937	25,334
Net product revenues	$ 1,809,395	$ 1,628,879	$ 1,401,243

The percentage of total revenues by customer who individually accounted for 10% or more of our total revenues were as follows:

	Year Ended December 31,		
	2024	2023	2022
Affiliates of Cencora, Inc. (formerly AmerisourceBergen Corporation)	18%	17%	18%
Affiliates of CVS Health Corporation	17%	17%	17%
Affiliates of McKesson Corporation	16%	17%	17%
Ipsen Pharma SAS	15%	8%	10%
Accredo Health, Incorporated	11%	12%	10%
Affiliates of Optum Specialty Pharmacy	9%	10%	10%

The percentage of trade receivables by customer who individually accounted for 10% or more of our trade receivables were as follows:

	December 31,	
	2024	2023
Affiliates of McKesson Corporation	23%	21%
Affiliates of CVS Health Corporation	20%	20%
Ipsen Pharma SAS	18%	19%
Affiliates of Cencora, Inc. (formerly AmerisourceBergen Corporation)	17%	17%
Cardinal Health, Inc.	10%	11%

Total revenues by geographic region were as follows (in thousands):

	Year Ended December 31,		
	2024	2023	2022
U.S.	$ 1,822,992	$ 1,645,749	$ 1,413,743
Europe	318,633	144,969	168,592
Japan	27,076	39,490	28,727
Total revenues	$ 2,168,701	$ 1,830,208	$ 1,611,062

Total revenues include net product revenues attributed to geographic regions based on ship-to location and license and collaboration services revenues attributed to geographic regions based on the location of our collaboration partners' headquarters.

Product Sales Discounts and Allowances

The activities and ending reserve balances for each significant category of discounts and allowances (which constitute variable consideration) were as follows (in thousands):

	Chargebacks, Discounts for Prompt Payment and Other	Other Customer Credits/Fees and Co-pay Assistance	Rebates	Total
Balance at December 31, 2022	$ 26,881	$ 14,924	$ 35,426	$ 77,231
Provision related to sales made in:				
Current period	419,975	56,349	170,788	647,112
Prior periods	295	(1,222)	(2,531)	(3,458)
Payments and customer credits issued	(421,930)	(50,330)	(163,785)	(636,045)
Balance at December 31, 2023	25,221	19,721	39,898	84,840
Provision related to sales made in:				
Current period	470,103	63,354	179,297	712,754
Prior periods	(891)	(2,044)	(968)	(3,903)
Payments and customer credits issued	(469,166)	(56,086)	(180,796)	(706,048)
Balance at December 31, 2024	$ 25,267	$ 24,945	$ 37,431	$ 87,643

The allowance for chargebacks, discounts for prompt payment and other are recorded as a reduction of trade receivables, net, and the remaining reserves are recorded as rebates and fees due to customers in the accompanying Consolidated Balance Sheets.

Contract Assets and Liabilities

We receive payments from our collaboration partners based on billing schedules established in each contract. Amounts are recorded as accounts receivable when our right to consideration is unconditional. We may also recognize revenue in advance of the contractual billing schedule and such amounts are recorded as a contract asset when recognized. We may be required to defer recognition of revenue for upfront and milestone payments until we perform our obligations under these arrangements, and such amounts are recorded as deferred revenue upon receipt or when due. For those contracts that have multiple performance obligations, contract assets and liabilities are reported on a net basis at the contract level. Contract assets are primarily related to Ipsen Pharma SAS (Ipsen) and contract liabilities are primarily related to deferred revenues from Takeda Pharmaceutical Company Limited (Takeda).

Contract assets and liabilities were as follows (in thousands):

	December 31,	
	2024	2023
Contract assets[(1)]	$ 369	$ 1,321
Contract liabilities:		
Current portion[(2)]	$ 2,739	$ 5,406
Non-current portion[(3)]	3,392	5,524
Total contract liabilities	$ 6,131	$ 10,930

[(1)] Presented in right-of-use assets and other non-current assets in the accompanying Consolidated Balance Sheets.
[(2)] Presented in other current liabilities in the accompanying Consolidated Balance Sheets.
[(3)] Presented in other non-current liabilities in the accompanying Consolidated Balance Sheets.

During the years ended December 31, 2024, 2023 and 2022, we recognized $6.0 million, $6.9 million and $8.1 million, respectively, in revenues that were included in the beginning deferred revenues balance for those years.

During the years ended December 31, 2024, 2023 and 2022, we recognized $351.9 million, $179.7 million and $161.6 million, respectively, in revenues for performance obligations satisfied in previous periods. Such revenues were primarily related to the recognition of license revenues for the achievement of milestones and royalty payments allocated to our license performance obligations for our collaborations with Ipsen, Takeda, Daiichi Sankyo and Genentech.

As of December 31, 2024, $40.5 million of the combined transaction prices for our Ipsen and Takeda collaborations were allocated to research and development services performance obligations that had not yet been satisfied. See "Note 4. Collaboration Agreements and Business Development Activities — Cabozantinib Commercial Collaborations — *Performance Obligations and Transaction Prices for our Ipsen and Takeda Collaborations"* for additional information about the expected timing to satisfy these performance obligations.

NOTE 4. COLLABORATION AGREEMENTS AND BUSINESS DEVELOPMENT ACTIVITIES

We have established multiple collaborations with leading biopharmaceutical companies for the commercialization and further development of our cabozantinib franchise. Additionally, we have made considerable progress under our existing research collaboration and in-licensing arrangements to further enhance our early-stage pipeline and expand our ability to discover, develop and commercialize novel therapies with the goal of providing new treatment options for cancer patients and their physicians. Historically, we also entered into other collaborations with leading biopharmaceutical companies pursuant to which we out-licensed other compounds and programs in our portfolio.

Under these collaborations, we are generally entitled to receive milestone and royalty payments, and for certain collaborations, to receive payments for product supply services, development cost reimbursements, and/or profit-sharing payments. See "Note 3. Revenues" for additional information on revenues recognized under our collaboration agreements during the years ended December 31, 2024, 2023 and 2022.

Cabozantinib Commercial Collaborations

Ipsen Collaboration

Description of the Collaboration

In February 2016, we entered into a collaboration and license agreement with Ipsen, which was subsequently amended, for the commercialization and further development of cabozantinib. Under the collaboration agreement, as amended, Ipsen received exclusive commercialization rights for current and potential future cabozantinib indications outside of the U.S. and Japan. We have also agreed to collaborate with Ipsen on the development of cabozantinib for current and potential future indications. The parties' efforts are governed through a joint steering committee and appropriate subcommittees established to guide and oversee the collaboration's operation and strategic direction; provided, however, that we retain final decision-making authority with respect to cabozantinib's ongoing development.

In the second quarter of fiscal year 2024, Ipsen opted into and is now co-funding the development costs for CABINET, a phase 3 pivotal study that evaluated cabozantinib versus placebo in patients with either advanced pNET) or advanced epNET who experienced progression after prior systemic therapy. Under the terms of the agreement, Ipsen is now obligated to reimburse us for its share of the CABINET global development costs. We determined that Ipsen's decision to opt into and co-fund the development costs for CABINET represented a contract modification for additional distinct services at its standalone selling price and therefore was treated as a separate contract under Topic 606. Accordingly, collaboration services revenues for the year ended December 31, 2024 includes a cumulative catch-up for Ipsen's share of global development costs incurred since the beginning of the study and through the opt-in date.

Unless earlier terminated, the collaboration agreement has a term that continues, on a product-by-product and country-by-country basis, until the latter of (1) the expiration of patent claims related to cabozantinib, (2) the expiration of regulatory exclusivity covering cabozantinib or (3) ten years after the first commercial sale of cabozantinib, other than COMETRIQ. A related supply agreement will continue in effect until expiration or termination of the collaboration agreement. The collaboration agreement may be terminated for cause by either party based on uncured material breach of either the collaboration agreement or the supply agreement by the other party, bankruptcy of the other party or for safety reasons. We may terminate the collaboration agreement if Ipsen challenges or opposes any patent covered by the collaboration agreement. Ipsen may terminate the collaboration agreement if the FDA or European Medicines Agency (EMA) orders or requires substantially all cabozantinib clinical trials to be terminated. Ipsen also has the right to terminate the collaboration agreement on a region-by-region basis after the first commercial sale of cabozantinib in advanced RCC in the given region. Upon termination by either party, all licenses granted by us to Ipsen will automatically terminate, and,

except in the event of a termination by Ipsen for our material breach, the licenses granted by Ipsen to us shall survive such termination and shall automatically become worldwide, or, if Ipsen were to terminate only for a particular region, then for the terminated region. Following termination by us for Ipsen's material breach, or termination by Ipsen without cause or because we undergo a change of control by a party engaged in a competing program, Ipsen is prohibited from competing with us for a period of time.

Consideration under the Collaboration

In consideration for the exclusive license and other rights contained in the collaboration agreement, including commercialization rights in Canada, we received aggregate upfront payments of $210.0 million from Ipsen in 2016. As of December 31, 2024, we have achieved aggregate milestones of $654.2 million related to regulatory, development and sales-based threshold by Ipsen since the inception of the collaboration agreement, including $164.7 million and $27.0 million in milestones achieved during the years ended December 31, 2024 and 2022, respectively.

As of December 31, 2024, we are eligible to receive additional regulatory and development milestone payments from Ipsen totaling an aggregate of $7.0 million as well as sales-based milestones of up to $200.0 million and CAD$23.5 million. We excluded these milestones from the transaction price as of December 31, 2024 because we determined such payments to be fully constrained under Topic 606 due to the fact that it was not probable that a significant reversal of cumulative revenue would not occur, given the inherent uncertainty of success with these milestones. We will adjust the constraint applied to the variable consideration at each reporting period as uncertain events are resolved or other changes in circumstances occur. See *"—Performance Obligations and Transaction Prices for our Ipsen and Takeda Collaborations"*, below, for additional information related to the revenue recognition for this collaboration.

We also receive royalty revenues on the net sales of cabozantinib by Ipsen outside of the U.S. and Japan. During the year ended December 31, 2024 and going forward, we are entitled to receive a tiered royalty of 22% to 26% on annual net sales, with separate tiers for Canada; these royalty tiers reset each calendar year.

Any variable consideration related to royalties and sales-based milestones will be recognized when the related sales occur as these amounts have been determined to relate to the relevant transferred license and therefore are recognized as the related sales occur.

We are required to pay a 3% royalty on all net sales of any product containing cabozantinib, including net sales by Ipsen.

We are responsible for funding cabozantinib-related development costs for those trials in existence at the time we entered into the collaboration agreement with Ipsen; global development costs for additional trials are shared between the parties, with Ipsen reimbursing us for 35% of such costs, provided Ipsen chooses to opt into such trials. Ipsen has opted into and is co-funding certain clinical trials, including: CheckMate -9ER, COSMIC-021, COSMIC-311, COSMIC-312, CONTACT-01, CONTACT-02 and CABINET.

We remain responsible for manufacturing and supply of cabozantinib for all development and commercialization activities under the collaboration agreement. Relatedly, we entered into a supply agreement with Ipsen to supply finished, labeled drug product to Ipsen for distribution in the territories outside of the U.S. and Japan for the term of the collaboration agreement as well as a quality agreement that provides respective quality responsibilities for the aforementioned supply. The product is supplied at our cost, as defined in the agreement. This agreement also requires us to maintain the global safety database for cabozantinib. To meet our obligations to regulatory authorities for the reporting of safety data from territories outside of U.S. and Japan from sources other than our sponsored global clinical development trials, we rely on data collected and reported to us by Japan.

Revenues from the Collaboration

Revenues under the collaboration agreement with Ipsen were as follows (in thousands):

	Year Ended December 31,		
	2024	2023	2022
License revenues	$ 317,026	$ 135,818	$ 133,732
Collaboration services revenues	1,607	9,151	34,860
Total collaboration revenues	$ 318,633	$ 144,969	$ 168,592

During the year ended December 31, 2024, we recognized $150.0 million in license revenues related to a commercial milestone from Ipsen upon its achievement of $600.0 million in cumulative net sales of cabozantinib over four consecutive quarters in its related Ipsen license territory and $2.2 million in license revenues for a commercial milestone from Ipsen upon its achievement of CAD$30.0 million in cumulative net sales of cabozantinib over four consecutive quarters in Canada. In addition, we recognized $10.8 million in license revenues and $0.6 million in collaboration services revenues, in connection with a $12.5 million regulatory milestone upon submission of a variation application to the EMA for evaluating cabozantinib versus placebo in patients with either advanced pNET or advanced epNET who experienced progression after prior systemic therapy.

As of December 31, 2024, $25.8 million of the transaction price was allocated to our research and development services performance obligation that has not yet been satisfied.

Takeda Collaboration

Description of the Collaboration

In January 2017, we entered into a collaboration and license agreement with Takeda, which was subsequently amended, to, among other things, modify the amount of reimbursements we receive, for costs associated with our required pharmacovigilance activities and milestones we are eligible to receive, as well as modify certain cost-sharing obligations related to the Japan-specific development costs associated with CONTACT-01 and CONTACT-02.

Takeda is responsible for a portion of the costs associated with the cabozantinib development plan's current and future trials, provided Takeda opts into such trials, and 100% of costs associated with the cabozantinib development activities that are exclusively for the benefit of Japan. Takeda has opted into and is co-funding CheckMate -9ER, certain cohorts of COSMIC-021, CONTACT-01 and CONTACT-02. Under the collaboration agreement, as amended, Takeda has exclusive commercialization rights for current and potential future cabozantinib indications in Japan, and the parties have agreed to collaborate on the clinical development of cabozantinib in Japan. The operation and strategic direction of the parties' collaboration is governed through a joint executive committee and appropriate subcommittees.

Unless earlier terminated, the collaboration agreement has a term that continues, on a product-by-product basis, until the earlier of (1) two years after first generic entry with respect to such product in Japan or (2) the later of (A) the expiration of patent claims related to cabozantinib and (B) the expiration of regulatory exclusivity covering cabozantinib in Japan. The collaboration agreement may be terminated for cause by either party based on uncured material breach by the other party, bankruptcy of the other party or for safety reasons. We may terminate the agreement if Takeda challenges or opposes any patent covered by the collaboration agreement. After the commercial launch of cabozantinib in Japan, Takeda may terminate the collaboration agreement upon twelve months' prior written notice following the third anniversary of the first commercial sale of cabozantinib in Japan. Upon termination by either party, all licenses granted by us to Takeda will automatically terminate, and the licenses granted by Takeda to us shall survive such termination and shall automatically become worldwide.

Consideration under the Collaboration

In consideration for the exclusive license and other rights contained in the collaboration agreement, we received an upfront payment of $50.0 million from Takeda in 2017. As of December 31, 2024, we have also achieved regulatory, development and commercial milestones in the aggregate of $138.0 million since the inception of the collaboration agreement, including $11.0 million in milestones achieved during the year ended December 31, 2023.

Under the collaboration agreement, as amended, we are eligible to receive additional regulatory and development milestone payments, without contractual limit, for additional potential future indications. We are further eligible to receive commercial milestones, including milestone payments earned for the first commercial sale of a product, of $108.0 million. We excluded these milestones from the transaction price as of December 31, 2024 because we determined such payments to be fully constrained under Topic 606 due to the fact that it was not probable that a significant reversal of cumulative revenue would not occur, given the inherent uncertainty of success with these milestones. We will adjust the constraint applied to the variable consideration at each reporting period as uncertain events are resolved or other changes in circumstances occur.

We also receive royalty revenues on the net sales of cabozantinib in Japan. We are entitled to receive a tiered royalty of 15% to 24% on the initial $300.0 million of net sales, and following this initial $300.0 million of net sales, we are then entitled to receive a tiered royalty of 20% to 30% on annual net sales thereafter; these 20% to 30% royalty tiers reset each calendar year. Any variable consideration related to royalties and sales-based milestones will be recognized when the related sales occur as these amounts have been determined to relate to the relevant transferred license and therefore are recognized as the related sales occur.

We are required to pay a 3% royalty on all net sales of any product containing cabozantinib, including net sales by Takeda.

Under the collaboration agreement, we are responsible for the manufacturing and supply of cabozantinib for all development and commercialization activities under the collaboration agreement. Relatedly, we entered into a clinical supply agreement covering the supply of cabozantinib to Takeda for the term of the collaboration agreement, as well as a quality agreement that provides respective quality responsibilities for the aforementioned supply. Furthermore, at the time we entered into the collaboration agreement, the parties also entered into a safety data exchange agreement, which defines each partner's responsibility for safety reporting. This agreement also requires us to maintain the global safety database for cabozantinib. To meet our obligations to regulatory authorities for the reporting of safety data from Japan from sources other than our sponsored global clinical development trials, we rely on data collected and reported to us by Takeda.

Revenues from the Collaboration

Revenues under the collaboration agreement with Takeda were as follows (in thousands):

	Year Ended December 31,		
	2024	2023	2022
License revenues	$ 12,915	$ 20,671	$ 11,335
Collaboration services revenues	8,455	13,543	12,903
Total collaboration revenues	$ 21,370	$ 34,214	$ 24,238

As of December 31, 2024, $14.7 million of the transaction price was allocated to our research and development services performance obligations that have not yet been satisfied.

Performance Obligations and Transaction Prices for our Ipsen and Takeda Collaborations

There is one remaining performance obligation for the Ipsen collaboration agreement: the research and development services, which includes certain committed studies for the development of cabozantinib, pharmacovigilance services and participation on various joint committees (as defined in the specific collaboration agreements). As part of the original contract, we also had a performance obligation associated with exclusive license for the commercialization and further development of cabozantinib, which was transferred in 2016.

There are two remaining performance obligations for the Takeda collaboration agreement: (1) the research and development services, which includes certain committed studies for the development of cabozantinib, pharmacovigilance services and participation on various joint committees (as defined in the specific collaboration agreements) and (2) the research and development services associated with CONTACT-01, CONTACT-02, and certain cohorts of COSMIC-021 studies. As part of the original contract, we had a performance obligation associated with the exclusive license for the commercialization and further development of cabozantinib, which was transferred in 2017.

We have allocated the transaction price for each of these collaborations to the originally identified performance obligations based on our best estimate of their relative standalone selling price. For the licenses, the estimate of the relative standalone selling price was determined using a discounted cash flow valuation utilizing forecasted revenues and costs. For research and development services the estimate of the relative standalone selling price was determined using an adjusted market assessment approach that relies on internal and external costs and market factors.

The portion of the transaction price allocated to our license performance obligation is recorded immediately as our license represents functional intellectual property that was transferred at a point in time. The portion of the transaction price allocated to our research and development services performance obligation is being recognized as revenue using the inputs method based on our internal development projected cost estimates through the current estimated patent expiration of cabozantinib in the European Union for the Ipsen collaboration and Japan for the Takeda collaboration, both of which are early 2030.

We adjust the constraint applied to the variable consideration for the collaboration agreements in each reporting period as uncertain events are resolved or other changes in circumstances occur and we allocate those changes in the transaction price between our performance obligations. During the years ended December 31, 2024, 2023 and 2022, the transaction price of the Ipsen and Takeda collaboration agreements increased as a result of the achievement of various milestones, and the reimbursements of research and development services related to committed and opt-in studies. We further updated the transaction price based upon the actual research and development services performed during the period and changes in our estimated reimbursements for our future research and development services. The portion of the increase in transaction price that was allocated to the previously satisfied performance obligations for the transfer of an intellectual property license was recognized during the period and the portion allocated to research and development services will be recognized in future periods as those services are delivered through early 2030. As of December 31, 2024, variable consideration related to the remaining unearned regulatory and development milestones for both agreements remained constrained due to the fact that it was not probable that a significant reversal of cumulative revenue would not occur.

Cabozantinib Development Collaborations

BMS

In February 2017, we entered into a clinical trial collaboration agreement with BMS for the purpose of exploring the therapeutic potential of cabozantinib in combination with BMS's immune checkpoint inhibitors (ICIs), nivolumab and/or ipilimumab, to treat a variety of types of cancer. As part of the collaboration, we are evaluating the triplet combination of cabozantinib, nivolumab and ipilimumab as a treatment option for RCC in the COSMIC-313 trial. Under the collaboration agreement with BMS, we may also evaluate these combinations in other phase 3 pivotal trials in various other tumor types.

Under the collaboration agreement with BMS, as amended, each party granted to the other a non-exclusive, worldwide (within the collaboration territory as defined in the collaboration agreement and its supplemental agreements), non-transferable, royalty-free license to use the other party's compounds in the conduct of each clinical trial. The parties' efforts are governed through a joint development committee established to guide and oversee the collaboration's operation. Each trial is conducted under a combination IND application, unless otherwise required by a regulatory authority. Each party is responsible for supplying finished drug product for the applicable clinical trial, and responsibility for the payment of costs for each such trial will be determined on a trial-by-trial basis. Unless earlier terminated, the collaboration agreement will remain in effect until the completion of all clinical trials under the collaboration, all related trial data has been delivered to both parties and the completion of any then agreed upon analysis. The collaboration agreement may be terminated for cause by either party based on uncured material breach by the other party, bankruptcy of the other party or for safety reasons. Upon termination by either party, the licenses granted to each party to conduct a combined therapy trial will terminate.

F. Hoffmann-La Roche Ltd. (Roche) Collaboration

In February 2017, we entered into a master clinical supply agreement with Roche for the purpose of evaluating cabozantinib and Roche's ICI, atezolizumab, in locally advanced or metastatic solid tumors. Under this agreement with Roche, in June 2017, we initiated COSMIC-021, a phase 1b dose escalation study that is evaluating the safety and tolerability of cabozantinib in combination with Roche's atezolizumab in patients with locally advanced or metastatic solid tumors, and in December 2018, we initiated COSMIC-312, a multicenter, randomized, controlled phase 3 pivotal trial evaluating cabozantinib in combination with atezolizumab versus sorafenib in previously untreated advanced HCC. We are the sponsor of both trials, and Roche is providing atezolizumab free of charge.

In December 2019, we entered into a joint clinical research agreement with Roche for the purpose of further evaluating the combination of cabozantinib with atezolizumab in patients with locally advanced or metastatic solid tumors, including in the phase 3 pivotal clinical trials in advanced non-small cell lung cancer (CONTACT-01), metastatic castration-resistant prostate cancer (CONTACT-02) and RCC (CONTACT-03). If a party to the joint clinical research agreement proposes any additional combined therapy trials beyond these phase 3 pivotal trials, the joint clinical research agreement provides that such proposing party must notify the other party and that if agreed to, any such additional combined therapy trial will become part of the collaboration, or if not agreed to, the proposing party may conduct such additional combined therapy trial independently, subject to specified restrictions set forth in the joint clinical research agreement.

In July 2020, a supplement to the joint clinical research agreement was signed amongst us, Roche and Takeda due to Takeda opting into fund the combined therapy trial of CONTACT-01 sponsored by Roche. Chugai was added as an affiliate of Roche. All parties including Chugai conduct combined therapy trials in Japan upon the terms of the joint clinical research agreement.

Under the joint clinical research agreement, each party granted to the other a non-exclusive, worldwide (excluding, in our case, territory already the subject of a license by us to Takeda), non-transferable, royalty-free license, with a right to sublicense (subject to limitations), to use the other party's intellectual property and compounds solely as necessary for the party to perform its obligations under the joint clinical research agreement. The parties' efforts will be governed through a joint steering committee established to guide and oversee the collaboration and the conduct of the combined therapy trials. Each party will be responsible for providing clinical supply of their drug for all combined therapy trials, and the cost of the supply will be borne by such party. The clinical trial expenses for each combined therapy trial agreed to be conducted jointly under the joint clinical research agreement will be shared equally between the parties, and the clinical trial expenses for each additional combined therapy trial not agreed to be conducted jointly under the joint clinical research agreement will be borne by the proposing party, except that the cost of clinical supply for all combined therapy trials will be borne by the party that owns the applicable product.

We determined the contract is within the scope of Topic 808 as it involves joint operating activities where both parties have active participation in the arrangement and are exposed to significant risks and rewards. Payments between us and Roche under this arrangement are not subject to other accounting literature. Payments due to Roche for our share of clinical trial costs incurred by Roche will be recorded as research and development expense and payments due from Roche for their share of clinical trial costs incurred by us will be recorded as a reduction of research and development expense.

Unless earlier terminated, the joint clinical research agreement provides that it will remain in effect until the completion of all combined therapy trials under the collaboration, the delivery of all related trial data to both parties, and the completion of any then agreed-upon additional analyses. The joint clinical research agreement may be terminated for cause by either party based on any uncured material breach by the other party, bankruptcy of the other party or for safety reasons. Upon termination by either party, the licenses granted to each party will terminate upon completion of any ongoing activities under the joint clinical research agreement.

Royalty Pharma

In October 2002, we established a product development and commercialization collaboration agreement with GlaxoSmithKline (GSK), that required us to pay a 3% royalty to GSK on the worldwide net sales of any product containing cabozantinib sold by us and our collaboration partners. Effective January 1, 2021, Royalty Pharma plc (Royalty Pharma) acquired from GSK all rights, title and interest in royalties on net product sales containing cabozantinib for non-U.S. markets for the full term of the royalty and for the U.S. market through September 2026, after which time U.S. royalties will revert back to GSK. Royalty fees earned by Royalty Pharma in connection with our sales of cabozantinib are included in cost of goods sold and as a reduction of collaboration services revenues for sales by our collaboration partners. Such royalty fees earned by Royalty Pharma were $75.5 million, $68.0 million and $58.2 million during the years ended December 31, 2024, 2023 and 2022, respectively.

Other Collaborations

Genentech Collaboration

We have out-licensed to Genentech under a worldwide collaboration agreement, the development and commercialization of cobimetinib, under the brand name COTELLIC. The terms of the collaboration agreement require that we share in the profits and losses received or incurred in connection with the commercialization of COTELLIC in the U.S. In

addition to our profit share in the U.S., we are entitled to low double-digit royalties on net sales of COTELLIC outside the U.S.

During the years ended December 31, 2024, 2023 and 2022, we recognized $13.6 million, $16.9 million and $12.5 million, in revenues from profits and losses on U.S commercialization and royalties on ex-U.S. sales under the collaboration agreement with Genentech and are included within license revenues on our Consolidated Statements of Income.

Merck Collaboration

In October 2024, we entered into a clinical development collaboration with MSD International Business GmbH, known as Merck within the United States and Canada (Merck), to evaluate zanzalintinib in combination with KEYTRUDA® (pembrolizumab) in SCCHN through our ongoing STELLAR-305 phase 3 pivotal trial, as well as in combination with WELIREG® (belzutifan), Merck's oral hypoxia-inducible factor-2α inhibitor, in a phase 1/2 trial and two phase 3 pivotal trials for the treatment of patients with renal cell carcinoma. Under the terms of the collaboration, Merck will supply KEYTRUDA for our ongoing phase 3 STELLAR-305 trial in SCCHN. In addition, Merck will sponsor a phase 1/2 trial and two phase 3 pivotal trials in RCC; Merck will fund one of these phase 3 studies, and we will co-fund the phase 1/2 trial and the other phase 3 study, as well as supply zanzalintinib and cabozantinib. We maintain all global commercial and marketing rights to zanzalintinib. We determined the contract is within the scope of Topic 808 as it involves joint operating activities where both parties have active participation in the arrangement and are exposed to significant risks and rewards. Payments between us and Merck under this arrangement are not subject to other accounting literature. Payments due to Merck for our share of clinical trial costs incurred by Merck will be recorded as research and development expenses within the Consolidated Statements of Income.

Research Collaborations, In-Licensing Arrangements and Other Business Development Activities

We enter into collaborative arrangements with other pharmaceutical or biotechnology companies to develop and commercialize oncology assets or other intellectual property. Our research collaborations and in-licensing arrangements are intended to enhance our early-stage pipeline and expand our ability to discover, develop and commercialize novel therapies with the goal of providing new treatment options for cancer patients and their physicians. Our research collaborations, in-licensing arrangements and other strategic transactions generally include upfront payments for the purchase or in-licensing of intellectual property, development, regulatory and commercial milestone payments and royalty payments, in each case contingent upon the occurrence of certain future events linked to the success of the asset in development. Certain of our research collaborations provide us exclusive options that give us the right to license programs or acquire the intellectual property developed under the research collaborations for further discovery and development. When we decide to exercise the options, we are required to pay an exercise fee and then assume the responsibilities for all subsequent development, manufacturing and commercialization.

As part of the 2024 Restructuring Plan (as defined below), we have terminated certain of our in-licensing collaboration arrangements, including Aurigene Oncology, Ltd., BioInvent International AB, Cybrexa Therapeutics LLC, NBE-Therapeutics AG and STORM Therapeutics LTD. The termination of these agreements was effective in April 2024. See "Note 13. Restructuring" for additional information. During the year ended December 31, 2024, we also discontinued certain programs including the development of in-process research and development technology assets acquired from GamaMabs Pharma SA, and we terminated a separate license agreement with Catalent, previously entered into in November 2022, for three target programs.

During the years ended December 31, 2024, 2023 and 2022, we recognized $69.2 million, $173.0 million and $203.9 million, respectively, within research and development expenses on the Consolidated Statements of Income, primarily related to upfront payments for the purchase or in-licensing of intellectual property, research and development funding and development milestone payments related to costs of intellectual property that have not yet reached technological feasibility and other fees.

As of December 31, 2024, in conjunction with these collaborative in-licensing arrangements and asset purchase agreements, we are subject to potential future development milestone payments of up to $441.5 million, regulatory milestone payments of up to $278.0 million, and commercial milestone payments of up to $2.4 billion, each in the aggregate per product or target, as well as royalties on future net sales of products.

NOTE 5. CASH AND MARKETABLE SECURITIES

Cash, Cash Equivalents and Marketable Securities

Cash, cash equivalents and marketable securities consisted of the following (in thousands):

	December 31, 2024			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Debt securities available-for-sale:				
Commercial paper	$ 172,891	$ —	$ —	$ 172,891
Corporate bonds	1,012,035	1,498	(2,167)	1,011,366
U.S. Treasury and government-sponsored enterprises	339,126	226	(959)	338,393
Municipal bonds	2,990	11	—	3,001
Total debt securities available-for-sale	1,527,042	1,735	(3,126)	1,525,651
Money market funds	145,690	—	—	145,690
Certificates of deposit	77,226	—	—	77,226
Total cash, cash equivalents and marketable securities	$ 1,749,958	$ 1,735	$ (3,126)	$ 1,748,567

	December 31, 2023			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Debt securities available-for-sale:				
Commercial paper	$ 214,016	$ —	$ —	$ 214,016
Corporate bonds	870,870	1,652	(4,277)	868,245
U.S. Treasury and government-sponsored enterprises	409,157	414	(2,250)	407,321
Municipal bonds	7,880	10	(49)	7,841
Total debt securities available-for-sale	1,501,923	2,076	(6,576)	1,497,423
Money market funds	154,287	—	—	154,287
Certificates of deposit	72,309	—	—	72,309
Total cash, cash equivalents and marketable securities	$ 1,728,519	$ 2,076	$ (6,576)	$ 1,724,019

Interest receivable was $14.9 million and $13.1 million as of December 31, 2024 and 2023, respectively, and is included in prepaid expenses and other current assets in the accompanying Consolidated Balance Sheets.

Realized gains and losses on the sales of marketable securities were immaterial during the years ended December 31, 2024, 2023 and 2022.

We manage credit risk associated with our marketable securities portfolio through our investment policy, which limits purchases to high-quality issuers and the amount of our portfolio that can be invested in a single issuer. The fair value and gross unrealized losses on debt securities available-for-sale in an unrealized loss position were as follows (in thousands):

	December 31, 2024					
	In an Unrealized Loss Position Less than 12 Months		In an Unrealized Loss Position 12 Months or Greater		Total	
	Fair Value	Gross Unrealized Losses	Fair value	Gross Unrealized Losses	Fair value	Gross Unrealized Losses
Corporate bonds	$ 370,065	$ (1,630)	$ 160,887	$ (537)	$ 530,952	$ (2,167)
U.S. Treasury and government-sponsored enterprises	125,224	(755)	56,984	(204)	182,208	(959)
Total	$ 495,289	$ (2,385)	$ 217,871	$ (741)	$ 713,160	$ (3,126)

	December 31, 2023					
	In an Unrealized Loss Position Less than 12 Months		In an Unrealized Loss Position 12 Months or Greater		Total	
	Fair Value	Gross Unrealized Losses	Fair value	Gross Unrealized Losses	Fair value	Gross Unrealized Losses
Corporate bonds	$ 255,958	$ (847)	$ 281,837	$ (3,430)	$ 537,795	$ (4,277)
U.S. Treasury and government-sponsored enterprises	163,339	(406)	155,452	(1,844)	318,791	(2,250)
Municipal bonds	—	—	5,951	(49)	5,951	(49)
Total	$ 419,297	$ (1,253)	$ 443,240	$ (5,323)	$ 862,537	$ (6,576)

There were 255 and 230 debt securities available-for-sale in an unrealized loss position as of December 31, 2024 and 2023, respectively. During the years ended December 31, 2024 and 2023, we did not record an allowance for credit losses or other impairment charges on our investment securities. Based upon our quarterly impairment review, we determined that the unrealized losses were not attributed to credit risk, but were primarily associated with changes in interest rates and market liquidity. Based on the scheduled maturities of our marketable securities, we determined that it was more likely than not that we will hold these marketable securities for a period of time sufficient for a recovery of our cost basis.

The fair values of debt securities available-for-sale by contractual maturity were as follows (in thousands):

	December 31,	
	2024	2023
Maturing in one year or less	$ 888,360	$ 768,706
Maturing after one year through five years	637,291	728,717
Total debt securities available-for-sale	$ 1,525,651	$ 1,497,423

NOTE 6. FAIR VALUE MEASUREMENTS

Fair value reflects the amounts that would be received upon sale of an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value hierarchy has the following three levels:

- Level 1 - quoted prices (unadjusted) in active markets for identical assets and liabilities;
- Level 2 - inputs other than level 1 that are observable either directly or indirectly, such as quoted prices in active markets for similar instruments or on industry models using data inputs, such as interest rates and prices that can

be directly observed or corroborated in active markets; and

- Level 3 - unobservable inputs that are supported by little or no market activity that are significant to the fair value measurement.

The classifications within the fair value hierarchy of our financial assets that were measured and recorded at fair value on a recurring basis were as follows (in thousands):

	December 31, 2024		
	Level 1	Level 2	Total
Commercial paper	$ —	$ 172,891	$ 172,891
Corporate bonds	—	1,011,366	1,011,366
U.S. Treasury and government-sponsored enterprises	—	338,393	338,393
Municipal bonds	—	3,001	3,001
Total debt securities available-for-sale	—	1,525,651	1,525,651
Money market funds	145,690	—	145,690
Certificates of deposit	—	77,226	77,226
Total financial assets carried at fair value	$ 145,690	$ 1,602,877	$ 1,748,567

	December 31, 2023		
	Level 1	Level 2	Total
Commercial paper	$ —	$ 214,016	$ 214,016
Corporate bonds	—	868,245	868,245
U.S. Treasury and government-sponsored enterprises	—	407,321	407,321
Municipal bonds	—	7,841	7,841
Total debt securities available-for-sale	—	1,497,423	1,497,423
Money market funds	154,287	—	154,287
Certificates of deposit	—	72,309	72,309
Total financial assets carried at fair value	$ 154,287	$ 1,569,732	$ 1,724,019

When available, we value marketable securities based on quoted prices for those financial instruments, which is a Level 1 input. Our remaining marketable securities are valued using third-party pricing sources, which use observable market prices, interest rates and yield curves observable at commonly quoted intervals for similar assets as observable inputs for pricing, which is a Level 2 input.

The carrying amount of our remaining financial assets and liabilities, which include receivables and payables, approximate their fair values due to their short-term nature.

Forward Foreign Currency Contracts

We have entered into forward foreign currency exchange contracts that are not designated as hedges for accounting purposes to hedge certain operational exposures for the changes in foreign currency exchange rates associated with assets or liabilities denominated in foreign currencies, primarily the Euro.

As of December 31, 2024, we had one forward contract outstanding to sell €3.6 million. The forward contract with a maturity of three months is recorded at fair value and is included in other current liabilities in the Consolidated Balance Sheets. The unrealized gain on the forward contract is immaterial as of December 31, 2024. The forward contract is considered a Level 2 in the fair value hierarchy of our fair value measurements. The net realized gains (losses) we recognized on the maturity of forward contracts were immaterial for the years ended December 31, 2024, 2023, respectively and $1.2 million for the year ended December 31, 2022. Realized and unrealized gains and losses on our forward contracts are included in other income (expense), net on our Consolidated Statements of Income.

NOTE 7. INVENTORY

Inventory consisted of the following (in thousands):

	December 31,	
	2024	2023
Raw materials	$ 2,784	$ 7,313
Work in process	60,316	59,422
Finished goods	8,629	9,581
Total	$ 71,729	$ 76,316
Balance Sheet classification:		
Current portion included in inventory	$ 22,388	$ 17,323
Long-term portion included in other long-term assets	49,341	58,993
Total	$ 71,729	$ 76,316

NOTE 8. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following (in thousands):

	Estimated Useful Lives	December 31,	
		2024	2023
Leasehold improvements	up to 15 years	$ 108,277	$ 89,038
Computer equipment and software	up to 3 years	15,671	19,795
Furniture and fixtures	up to 7 years	22,865	24,919
Laboratory equipment	5 years	70,435	50,904
Construction in progress		2,875	24,465
Total property and equipment		220,123	209,121
Less: accumulated depreciation and amortization		(100,732)	(80,390)
Total property and equipment, net		$ 119,391	$ 128,731

Depreciation and amortization expense was $28.8 million, $25.7 million and $20.9 million during the years ended December 31, 2024, 2023 and 2022, respectively.

NOTE 9. STOCKHOLDERS' EQUITY

Stock-based compensation

We allocated the stock-based compensation expense for our equity incentive plans and our ESPP as follows (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Research and development	$ 30,670	$ 34,320	$ 45,350
Selling, general and administrative	63,166	72,025	62,224
Total stock-based compensation expense	$ 93,836	$ 106,345	$ 107,574

	Year Ended December 31,		
	2024	2023	2022
Stock options	$ 6,035	$ 7,771	$ 12,790
Restricted stock units	81,130	70,462	69,775
Performance stock units	3,058	23,938	21,616
Employee stock purchase plan	3,613	4,174	3,393
Total stock-based compensation expense	$ 93,836	$ 106,345	$ 107,574

We have an equity incentive plan under which we granted stock options and RSUs, including PSUs, to employees and directors. As of December 31, 2024, 28.6 million shares were available for grant under the Exelixis, Inc. 2017 Equity Incentive Plan (as amended and restated, the 2017 Plan). The share reserve is reduced by 1 share for each share issued pursuant to a stock option and 2 shares for full value awards, including RSUs and PSUs.

The Board of Directors delegated responsibility for administration of our equity incentive plan to the Compensation Committee of our Board of Directors, including the authority to determine the term, exercise price and vesting requirements of each grant. Stock options granted to our employees and directors generally have a four-year vesting term and a one-year vesting term, respectively, an exercise price equal to the fair market value on the date of grant, and a seven-year life from the date of grant. RSUs granted to our employees and directors generally have a four-year vesting term and a one-year vesting term, respectively. PSUs granted pursuant to our equity incentive plans vest upon specified service conditions and the achievement of a performance target or market condition.

We have adopted a Change in Control and Severance Benefit Plan for certain executive officers. Eligible Change in Control and Severance Benefit Plan participants include employees with the title of vice president and above. If a participant's employment is terminated without cause during a period commencing three months before and ending fifteen months following a change in control, as defined in the plan document, then the Change in Control and Severance Benefit Plan participant is entitled to have the vesting of all their outstanding equity awards accelerated and the exercise period for their stock options extended to no more than one year.

On May 30, 2024, at the 2024 Annual Meeting of Stockholders, our stockholders approved the amendment and restatement of the Exelixis, Inc. 2000 Employee Stock Purchase Plan (as amended and restated, the Amended ESPP). The amendment and restatement increased the share reserve by 6.0 million shares. Our Amended ESPP allows for qualified employees (as defined in the Amended ESPP) to purchase shares of our common stock at a price equal to the lower of 85% of the closing price at the beginning of the offering period or 85% of the closing price at the end of each six-month purchase period. As of December 31, 2024, we had 7.0 million shares available for issuance under our Amended ESPP. Pursuant to the Amended ESPP, we issued 0.7 million, 0.9 million and 0.6 million shares of common stock at an average price per share of $18.23, $14.56 and $16.63 during the years ended December 31, 2024, 2023 and 2022, respectively. Cash received from purchases under the Amended ESPP for the years ended December 31, 2024, 2023 and 2022 was $12.1 million, $12.7 million and $10.1 million, respectively.

We used a Black-Scholes Merton option pricing model to value stock options and ESPP purchases. The weighted average grant-date fair value per share of stock options and ESPP purchases were as follows:

	Year Ended December 31,		
	2024	2023	2022
Stock options	$ 9.79	$ 9.45	$ 8.36
ESPP	$ 6.39	$ 4.67	$ 5.80

The grant-date fair value of stock option grants and ESPP purchases was estimated using the following weighted average assumptions:

	Year Ended December 31,		
	2024	2023	2022
Stock options:			
Risk-free interest rate	4.40%	4.14%	2.35%
Dividend yield	—%	—%	—%
Volatility	39%	44%	48%
Expected life	5.6 years	5.6 years	4.6 years
ESPP:			
Risk-free interest rate	5.15%	5.07%	1.49%
Dividend yield	—%	—%	—%
Volatility	34%	40%	45%
Expected life	6 months	6 months	6 months

We considered both implied and historical volatility in developing our estimate of expected volatility. The assumption for the expected life of stock options is based on historical exercise patterns and post-vesting termination behavior. The risk-free interest rate is based on U.S. Treasury rates with the same or similar term as the underlying award. Our dividend rate is based on historical experience and our investors' current expectations.

The fair value of RSUs, including PSUs, was based on the closing price of the underlying common stock on the date of grant.

Activity for stock options during the year ended December 31, 2024 was as follows (in thousands**,** except per share amounts):

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Stock options outstanding at December 31, 2023	8,208	$ 21.24	2.7 years	$ 24,115
Granted	124	$ 22.46		
Exercised	(3,051)	$ 21.78		
Cancelled	(665)	$ 23.22		
Stock options outstanding at December 31, 2024	4,616	$ 20.64	2.5 years	$ 61,551
Stock options exercisable at December 31, 2024	4,106	$ 20.58	2.2 years	$ 54,974

As of December 31, 2024, there was $3.9 million of unrecognized compensation expense related to our unvested stock options. The compensation expense for the unvested stock options will be recognized over a weighted-average period of 1.6 years.

The aggregate intrinsic value in the table above represents the total intrinsic value (the difference between our closing stock price on the last trading day of fiscal year 2024 and the exercise prices, multiplied by the number of in-the-money stock options) that would have been received by the stock option holders had all stock option holders exercised their stock options on December 31, 2024. The total intrinsic value of stock options exercised during the years ended December 31, 2024, 2023 and 2022 was $16.7 million, $16.7 million and $36.5 million, respectively. Cash received from stock option exercises during the years ended December 31, 2024, 2023 and 2022 was $49.6 million, $20.8 million and $13.9 million, respectively.

Activity for RSUs during the year ended December 31, 2024 was as follows (in thousands, except per share amounts):

	Shares	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
RSUs outstanding at December 31, 2023	11,874	$ 22.72	1.7 years	$ 284,856
Awarded	5,974	$ 21.74		
Vested and released	(2,845)	$ 20.71		
Forfeited	(2,063)	$ 21.86		
RSUs outstanding at December 31, 2024	12,940	$ 22.84	1.5 years	$ 439,580

As of December 31, 2024, there was $161.1 million of unrecognized compensation expense related to our unvested RSUs which will be recognized over a weighted-average period of 2.2 years.

Activity for PSUs during the year ended December 31, 2024 was as follows (in thousands, except per share amounts):

	Shares	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
PSUs outstanding at December 31, 2023	3,891	$ 23.60	1.3 years	$ 93,351
Awarded	192	$ 24.54		
Vested and released	(901)	$ 23.87		
Forfeited	(2,733)	$ 23.42		
PSUs outstanding at December 31, 2024	449	$ 24.54	0.1 years	$ 15,257

In February 2024, we awarded to certain employees an aggregate of 1.3 million RSUs (the target number) that are subject to a total shareholder return (TSR) market condition (the 2024 TSR-based RSUs). The TSR market condition is based on our relative TSR percentile rank compared to companies in the Nasdaq Biotechnology Index during the performance period, which is December 30, 2023 through January 1, 2027. Depending on the results relative to the TSR market condition, the holders of the 2024 TSR-based RSUs may earn up to 175% of the target number of shares. 50% of the shares earned pursuant to the 2024 TSR-based RSU awards will vest shortly after the end of the performance period, and the remainder will vest approximately one year later, subject to an employee's continuous service. These 2024 TSR-based RSUs will be forfeited if the market condition at or above a threshold level is not achieved at the end of the performance period on January 1, 2027.

In April 2023, we awarded to certain employees an aggregate of 0.8 million RSUs (the target amount) that are subject to a TSR market condition (the 2023 TSR-based RSUs). The TSR market condition is based on our relative TSR percentile rank compared to companies in the Nasdaq Biotechnology Index during the performance period, which is December 31, 2022 through January 2, 2026. Depending on the results relative to the TSR market condition, the holders of the 2023 TSR-based RSUs may earn up to 175% of the target number of shares. 50% of the shares earned pursuant to the 2023 TSR-based RSU awards will vest shortly after the end of the performance period, and the remainder will vest approximately one year later, subject to an employee's continuous service. These 2023 TSR-based RSUs will be forfeited if the market condition at or above a threshold level is not achieved at the end of the performance period on January 2, 2026.

In March 2022, we awarded to certain employees an aggregate of 1.0 million RSUs (the target amount) that are subject to a TSR market condition (the 2022 TSR-based RSUs). The TSR market condition is based on our relative TSR percentile rank compared to companies in the Nasdaq Biotechnology Index during the performance period, which is January 1, 2022 through January 3, 2025. Depending on the results relative to the TSR market condition, the holders of the 2022 TSR-based RSUs may earn up to 175% of the target number of shares. At the end of fiscal year 2024 (end of the performance period), the TSR market condition was achieved at 175% level, resulting in 1.5 million shares earned (175% of the 2022 TSR-based RSUs target amount, net of forfeitures). 50% percent of the shares earned subject to the market

conditions vested shortly after the end of the performance period, and the remainder will vest approximately one year later, subject to an employee's continuous service.

In March 2021, we awarded to certain employees an aggregate of 1.0 million PSUs (the 2021 target amount), subject to a performance and a market condition (the 2021 PSUs). Pursuant to the terms of 2021 PSUs, the holders of the awards may earn up to 200% of the 2021 PSUs target amount, depending on the level of achievement of the performance condition related to certain net product revenues and a TSR market condition. The TSR market condition for the 2021 PSUs was based on our relative TSR percentile rank compared to companies in the Nasdaq Biotechnology Index during the performance period, which was from January 2, 2021 through December 29, 2023. The performance condition of net product revenues relative to the 2021 PSUs was achieved at target level in the first quarter of 2023, representing 100% of the 2021 PSUs target amount. At the end of fiscal year 2023 (end of the performance period), the TSR market condition was achieved at 125% level, resulting in 1.0 million shares earned (125% of the 2021 PSUs target amount, net of forfeitures). 50% percent of the shares earned subject to the performance and market conditions vested shortly after the end of the performance period, and the remainder will vest approximately one year, later subject to an employee's continuous service.

We used a Monte Carlo simulation model and the following weighted-average assumptions to determine the weighted-average grant date fair value of $20.19 per share for the 2024 TSR-based RSUs, $26.05 per share for the 2023 TSR-based RSUs, $33.17 per share for the 2022 TSR-based RSUs, and $24.54 per share for the 2021 PSUs:

	2024 TSR-Based RSUs	2023 TSR-Based RSUs	2022 TSR-Based RSUs	2021 PSUs
Fair value of Exelixis common stock on grant date	$ 21.71	$ 19.48	$ 20.70	$ 21.31
Expected volatility	36.68%	40.26%	46.85%	49.21%
Risk-free interest rate	4.42%	3.75%	1.59%	0.29%
Dividend yield	—%	—%	—%	—%

The Monte Carlo simulation model assumed correlations of returns of the stock prices of Exelixis common stock and the common stock of a peer group of companies and historical stock price volatility of the peer group of companies. The valuation model also used terms based on the length of the performance period and compound annual growth rate goals for TSR based on the provisions of the awards.

During the year ended December 31, 2020, we awarded 2.3 million PSUs (the target amount) that will vest upon the achievement of performance targets related to (i) clinical trial positive top-line results and (ii) product approvals by the FDA (the 2020 PSUs). Pursuant to the terms of the 2020 PSUs, employees may earn up to 200% of the target amount depending on the volume and timing of achievement of the performance targets. The 2020 PSUs will be forfeited if the performance targets are not met by December 31, 2024. In the third quarter of 2021, we achieved a performance condition for a product approval by the FDA relative to the 2020 PSUs, representing 25% of the target amount. In the third quarter of 2022, we achieved a performance condition for positive top-line results by the FDA relative to the 2020 PSUs, representing 25% of the target amount, and in the third quarter of 2023, we achieved additional performance conditions for positive top-line results by the FDA relative to the 2020 PSUs, representing an additional 50% of the target amount. At the end of the performance period, on December 31, 2024, shares assigned to the performance conditions previously achieved were fully vested and there was no unrecognized compensation expense for the performance conditions achieved. There were 1.6 million shares forfeited for performance conditions that were not achieved by the end of the performance period.

Expense recognition for PSUs commences when it is determined that attainment of the performance target is probable. As of December 31, 2024, all of the outstanding PSUs relate to awards for which we achieved the performance target. As of December 31, 2024, the remaining unrecognized compensation expense for the PSUs achieved was $0.3 million, which will be recognized over a weighted-average period of 0.1 years.

Exelixis, Inc. 401(k) Plan (the 401(k) Plan)

We sponsor the 401(k) Plan under which we make matching cash contributions to our employees' 401(k) accounts. We recorded compensation expense of $15.0 million, $13.9 million and $11.7 million for the years ended December 31, 2024, 2023 and 2022, respectively, for matching contributions.

Common Stock Repurchases

In January 2024, our Board of Directors authorized a stock repurchase program to acquire up to $450.0 million of our outstanding common stock before the end of 2024. As of June 30, 2024, we completed the repurchase of 20.3 million shares of common stock for an aggregate purchase price of $450.0 million pursuant to our stock repurchase program. In August 2024, our Board of Directors authorized a stock repurchase program to acquire up to $500.0 million of our outstanding common stock before the end of 2025. Under this program, as of December 31, 2024, we repurchased 6.1 million shares of common stock for an aggregate purchase price of $205.6 million. As of December 31, 2024, approximately $294.4 million remained available for future stock repurchases before the end of 2025.

Stock repurchases under the program may be made from time to time through a variety of methods, which may include open market purchases, in block trades, Rule 10b5-1 trading plans, accelerated share repurchase transactions, exchange transactions, or any combination of such methods. The timing and amount of any stock repurchases under the stock repurchase program will be based on a variety of factors, including ongoing assessments of the capital needs of the business, alternative investment opportunities, the market price of our common stock and general market conditions. The program does not obligate us to acquire any particular amount of our common stock, and the stock repurchase program may be modified, suspended or discontinued at any time without prior notice.

NOTE 10. PROVISION FOR INCOME TAXES

Our income before income taxes is derived solely from within the U.S. Our provision for income taxes was as follows (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Current:			
Federal	$ 201,890	$ 167,954	$ 100,525
State	17,941	15,011	11,903
Total current tax expense	$ 219,831	$ 182,965	$ 112,428
Deferred:			
Federal	$ (52,433)	$ (123,486)	$ (54,223)
State	(7,025)	(9,723)	(6,135)
Total deferred tax expense	(59,458)	(133,209)	(60,358)
Provision for income taxes	$ 160,373	$ 49,756	$ 52,070

The reconciliation of the U.S. federal income tax provision at the statutory federal income tax rate of 21% for each of the years ended December 31, 2024, 2023 and 2022, respectively, to our provision for income taxes was as follows (in thousands):

	Year Ended December 31,		
	2024	2023	2022
U.S. federal income tax provision at statutory rate	$ 143,144	$ 54,080	$ 49,213
State tax expense	12,240	(1,487)	(2,632)
Change in valuation allowance	(3,617)	5,770	7,162
Research credits	(10,997)	(23,714)	(14,130)
Stock-based compensation	665	1,066	(2,864)
Non-deductible executive compensation	7,094	7,019	4,549
Branded prescription drug fee	4,633	4,968	3,855
Non-deductible warrant purchase	—	—	6,300
Other	7,211	2,054	617
Provision for income taxes	$ 160,373	$ 49,756	$ 52,070

Deferred tax assets and liabilities reflect the net tax effects of net operating loss and tax credit carryforwards and temporary differences between the carrying amounts of assets and liabilities for financial reporting and the amounts used for income tax purposes.

Our deferred tax assets and liabilities were as follows (in thousands):

	December 31,	
	2024	2023
Deferred tax assets:		
Net operating loss and capital loss carryforwards	$ 39,877	$ 29,512
Tax credit carryforwards	39,572	39,640
Depreciation and amortization	349,058	313,679
Stock-based compensation	17,791	24,592
Lease liabilities	49,137	49,971
Accruals and reserves not currently deductible	40,858	30,068
Other assets	9,049	10,730
Total deferred tax assets	545,342	498,192
Valuation allowance	(86,029)	(83,001)
Net deferred tax assets	459,313	415,191
Deferred tax liabilities:		
Lease right-of-use assets	(39,286)	(54,046)
Net deferred taxes	$ 420,027	$ 361,145

As of December 31, 2024 and 2023, we continue to carry a valuation allowance of $86.0 million and $83.0 million, respectively, against our California state deferred tax assets and federal and state capital loss carryforwards. The valuation allowance increased by $3.0 million and $5.8 million during the years ended December 31, 2024 and 2023, respectively.

At December 31, 2024, we had state net operating loss carryforwards of approximately $407.0 million, which expire in the years 2025 through 2036, and California research and development tax credits of approximately $55.0 million, which do not expire.

Under the Internal Revenue Code and similar state provisions, certain substantial changes in our ownership could result in an annual limitation on the amount of net operating loss and credit carryforwards that can be utilized in future years to offset future taxable income. The annual limitation may result in the expiration of net operating losses and credit carryforwards before utilization. We completed a Section 382 analysis through December 31, 2024, and concluded that an ownership change, as defined under Section 382, had not occurred.

The following table summarizes the activity related to our unrecognized tax benefits (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Beginning balance	$ 115,766	$ 87,706	$ 83,583
Change relating to prior year provision	(1,994)	631	715
Change relating to current year provision	13,796	32,137	4,129
Reductions based on the lapse of the applicable statutes of limitations	(68)	(4,708)	(721)
Ending balance	$ 127,500	$ 115,766	$ 87,706

As of December 31, 2024, we had $127.5 million in unrecognized tax benefits, of which $61.5 million would reduce our income tax provision and effective tax rate, if recognized. We have elected to record interest and penalties in the accompanying Consolidated Statements of Income as a component of provision for income taxes. In the year ended December 31, 2024, the total amount of gross interest and penalties accrued was $8.1 million. In the year ended December 31, 2023 and 2022, interest and penalties were nominal or zero. Both the unrecognized tax benefits and the associated

interest and penalties are not expected to result in payment or receipt of cash within one year and are therefore classified as other non-current liabilities in the Consolidated Balance Sheets.

We file U.S. and state income tax returns in jurisdictions with varying statues of limitations during which such tax returns may be audited and adjusted by the relevant tax authorities. The tax years 2002 and onwards generally remain subject to examination by federal and most state tax authorities to the extent net operating losses and credits generated during these periods are being utilized in the open tax periods. We estimate that it is reasonably possible that our gross unrecognized tax benefits, exclusive of interest, could decrease by up to approximately $10.7 million in the next 12 months, as a result of various audit closures, settlements, and expiration of statute of limitations.

NOTE 11. NET INCOME PER SHARE

Net income per share - basic and diluted, were computed as follows (in thousands, except per share amounts):

	Year Ended December 31,		
	2024	2023	2022
Numerator:			
Net income	$ 521,267	$ 207,765	$ 182,282
Denominator:			
Weighted-average common shares outstanding - basic	290,030	318,151	321,526
Dilutive securities	6,102	3,313	3,030
Weighted-average common shares outstanding - diluted	296,132	321,464	324,556
Net income per share - basic	$ 1.80	$ 0.65	$ 0.57
Net income per share - diluted	$ 1.76	$ 0.65	$ 0.56

Basic net income per share is computed using the weighted-average number of common shares outstanding during the period. The diluted net income per share is computed using the weighted-average number of shares and dilutive potential common shares outstanding during the period. Dilutive shares outstanding includes the dilutive effect of in-the-money options, unvested RSUs, and unvested PSUs when the performance condition is met. The dilutive effect of such equity awards is calculated based on the average share price for each fiscal period using the treasury stock method. Certain potential common shares were excluded from our calculation of weighted-average common shares outstanding - diluted because either they would have had an anti-dilutive effect on net income per share or they were related to shares from PSUs and RSUs with market conditions that were contingently issuable and the contingency had not been satisfied at the end of the reporting period. See “Note 9. Stockholders’ Equity” for a further description of our equity awards.

The weighted-average potential common shares excluded from our calculation were as follows (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Anti-dilutive securities and contingently issuable shares excluded	5,708	11,703	17,063

NOTE 12. COMMITMENTS AND CONTINGENCIES

Leases

We have operating leases for our corporate headquarters in Alameda, California and in Greater Philadelphia area which includes both office and laboratory space totaling approximately 674,000 square feet with lease terms ending in 2025 through 2037. Certain of our leases include options to renew the lease or to early terminate the lease. As of December 31, 2024, we considered whether these options to renew or early terminate were reasonably certain of exercise in determining the related lease terms.

Impairment of Long-Lived Assets

In connection with our 2024 Restructuring Plan, as discussed in “Note 13. Restructuring”, we exited two leases in

the Greater Philadelphia area pertaining to approximately 40,000 square feet of leased premises and performed an impairment analysis for these asset groups, primarily composed of right-of-use assets, leasehold improvements, and certain property and equipment. We reassessed the lease term for one of the leases in the Greater Philadelphia area and concluded we were reasonably certain to exercise our right to early terminate the lease and reduced our right-of-use asset and lease liability by $3.3 million. In connection with the restructuring plan, we recognized $12.7 million of non-cash impairment charge during the year ended December 31, 2024, to reduce the carrying value of these long-lived assets at their fair value. The impairment charge is presented in restructuring in the accompanying Consolidated Statements of Income.

During fiscal 2024, we evaluated our plans for the Alameda leased facilities and listed certain buildings for sublease. As a result, we determined the related right-of-use assets and leasehold improvements should be evaluated for impairment as separate asset groups. We concluded that these asset groups were not recoverable and we recognized $51.7 million of non-cash impairment charge and reduced the carrying value of our right-of-use assets pertaining to approximately 215,000 square feet of leased premises, reduced the leasehold improvements and certain property and equipment, to their estimated fair value. The estimated fair value was determined using an income approach comprised of projected discounted cash flows that included certain Level 3 inputs, such as sublease income and discount rates. The assumptions associated with sublease income and discount rates are subject to risks and uncertainties and could materially differ from our estimates. The impairment charge is presented in impairment of long-lived assets in the accompanying Consolidated Statements of Income.

The balance sheet classification of our operating lease assets and liabilities were as follows (in thousands):

	December 31,	
	2024	2023
Assets:		
Right-of-use assets included in other non-current assets	$ 172,564	$ 233,244
Liabilities:		
Current portion included in other current liabilities	$ 25,011	$ 25,715
Non-current portion of operating lease liabilities	190,823	189,944
Total operating lease liabilities	$ 215,834	$ 215,659

The components of operating lease costs were as follows (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Operating lease cost	$ 27,461	$ 28,976	$ 18,315
Variable lease cost	9,276	7,068	3,098
Total operating lease costs	$ 36,737	$ 36,044	$ 21,413

Lease costs for leases with initial terms less than 1 year were immaterial for the years ended December 31, 2024, 2023 and 2022, respectively.

Cash paid for operating leases which were included in net cash provided by operating activities in our Consolidated Statements of Cash Flows were as follows (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Cash paid for operating leases	$ 26,341	$ 19,559	$ 11,430

The lease term and discount rate for operating leases were as follows:

	December 31,	
	2024	2023
Weighted-average remaining lease term (in years)	10.6 years	11.4 years
Weighted-average discount rate	5.3 %	5.3 %

As of December 31, 2024, the maturities of our operating lease liabilities were as follows (in thousands):

Year Ended December 31,	Amount
2025	$ 26,526
2026	28,520
2027	24,301
2028	25,029
2029	25,777
Thereafter	155,585
Total lease payments	285,738
Less:	
Imputed interest	(69,904)
Operating lease liabilities	$ 215,834

Legal Proceedings

MSN I ANDA Litigation

In September 2019, we received a notice letter regarding an Abbreviated New Drug Application (ANDA) submitted to the FDA by MSN Pharmaceuticals, Inc. (individually and collectively with certain of its affiliates, including MSN Laboratories Private Limited, referred to as MSN), requesting approval to market a generic version of CABOMETYX tablets. MSN's initial notice letter included a Paragraph IV certification with respect to our U.S. Patents No. 8,877,776 (salt and polymorphic forms), 9,724,342 (formulations), 10,034,873 (methods of treatment) and 10,039,757 (methods of treatment), which are listed in the Approved Drug Products with Therapeutic Equivalence Evaluations, also referred to as the Orange Book, for CABOMETYX. MSN's initial notice letter did not provide a Paragraph IV certification against U.S. Patents No. 7,579,473 (composition of matter) or 8,497,284 (methods of treatment), each of which is listed in the Orange Book. On October 29, 2019, we filed a complaint in the United States District Court for the District of Delaware (the Delaware District Court) for patent infringement against MSN asserting infringement of U.S. Patent No. 8,877,776 arising from MSN's ANDA filing with the FDA. On November 20, 2019, MSN filed its response to the complaint, alleging that the asserted claims of U.S. Patent No. 8,877,776 are invalid and not infringed. On May 5, 2020, we received notice from MSN that it had amended its ANDA to include additional Paragraph IV certifications. In particular, the May 5, 2020 amended ANDA requested approval to market a generic version of CABOMETYX tablets prior to expiration of two previously unasserted CABOMETYX patents: U.S. Patents No. 7,579,473 and 8,497,284. On May 11, 2020, we filed a complaint in the Delaware District Court for patent infringement against MSN asserting infringement of U.S. Patents No. 7,579,473 and 8,497,284 arising from MSN's amended ANDA filing with the FDA. Neither of our complaints have alleged infringement of U.S. Patents No. 9,724,342, 10,034,873 and 10,039,757. On May 22, 2020, MSN filed its response to the complaint, alleging that the asserted claims of U.S. Patents No. 7,579,473 and 8,497,284 are invalid and not infringed. On March 23, 2021, MSN filed its First Amended Answer and Counterclaims (amending its prior filing from May 22, 2020), seeking, among other things, a declaratory judgment that U.S. Patent No. 9,809,549 (salt and polymorphic forms) is invalid and would not be infringed by MSN if its generic version of CABOMETYX tablets were approved by the FDA. U.S. Patent No. 9,809,549 is not listed in the Orange Book. On April 7, 2021, we filed our response to MSN's First Amended Answer and Counterclaims, denying, among other things, that U.S. Patent No. 9,809,549 is invalid or would not be infringed. The two lawsuits comprising this litigation (collectively referred to as MSN I), numbered Civil Action Nos. 19-02017 and 20-00633, were consolidated in April 2021.

On October 1, 2021, pursuant to a stipulation between us and MSN, the Delaware District Court entered an order that (i) MSN's submission of its ANDA constitutes infringement of certain claims relating to U.S. Patents No. 7,579,473 and 8,497,284, if those claims are not found to be invalid, and (ii) upon approval, MSN's commercial manufacture, use, sale or

offer for sale within the U.S., and importation into the U.S., of MSN's proposed ANDA product prior to the expiration of U.S. Patents No. 7,579,473 and 8,497,284 would also infringe certain claims of each patent, if those claims are not found to be invalid. Then, on October 12, 2021, pursuant to a separate stipulation between us and MSN, the Delaware District Court entered an order dismissing MSN's counterclaim with respect to U.S. Patent No. 9,809,549. In our MSN I complaints, we sought, among other relief, an order that the effective date of any FDA approval of MSN's ANDA be a date no earlier than the expiration of all of U.S. Patents No. 7,579,473, 8,497,284 and 8,877,776, the latest of which expires on October 8, 2030, and equitable relief enjoining MSN from infringing these patents. To streamline the case, the parties narrowed their assertions. On April 8, 2022, MSN withdrew its validity challenge to U.S. Patent No. 8,877,776. On April 14, 2022, we agreed not to assert U.S. Patent No. 8,497,284 at trial and MSN, correspondingly, agreed to withdraw its validity challenges to U.S. Patent No. 8,497,284, as well as claims 1-4 and 6-7 of U.S. Patent No. 7,579,473. As a result of this narrowing, the trial addressed two issues: (1) infringement of claim 1 of the U.S. Patent No. 8,877,776; and (2) validity of claim 5 of the U.S. Patent No. 7,579,473. A bench trial for MSN I occurred in May 2022, and on January 19, 2023, the Delaware District Court issued a ruling rejecting MSN's invalidity challenge to U.S. Patent No. 7,759,473. The Delaware District Court also ruled that MSN's proposed ANDA product does not infringe U.S. Patent No. 8,877,776. In accordance with these rulings, the Delaware District Court entered judgment that the effective date of any final FDA approval of MSN's ANDA shall not be a date earlier than August 14, 2026, the expiration date of U.S. Patent No. 7,759,473. Final judgment was entered on January 30, 2023. This ruling in MSN I did not impact our separate MSN II lawsuit (as defined below).

MSN II ANDA Litigation

On January 11, 2022, we received notice from MSN that it had further amended its ANDA to assert additional Paragraph IV certifications. In particular, the January 11, 2022 amended ANDA requested approval to market a generic version of CABOMETYX tablets prior to expiration of three previously-unasserted CABOMETYX patents that are now listed in the Orange Book: U.S. Patents No. 11,091,439 (crystalline salt forms), 11,091,440 (pharmaceutical composition) and 11,098,015 (methods of treatment). On February 23, 2022, we filed a complaint in the Delaware District Court for patent infringement against MSN asserting infringement of U.S. Patents No. 11,091,439, 11,091,440 and 11,098,015 arising from MSN's further amendment of its ANDA filing with the FDA. On February 25, 2022, MSN filed its response to the complaint, alleging that the asserted claims of U.S. Patents No. 11,091,439, 11,091,440 and 11,098,015 are invalid and not infringed. On June 7, 2022, we received notice from MSN that it had further amended its ANDA to assert an additional Paragraph IV certification. As currently amended, MSN's ANDA now requests approval to market a generic version of CABOMETYX tablets prior to expiration of a previously-unasserted CABOMETYX patent that is now listed in the Orange Book: U.S. Patent No. 11,298,349 (pharmaceutical composition). On July 18, 2022, we filed a complaint in the Delaware District Court for patent infringement against MSN asserting infringement of U.S. Patent No. 11,298,349 arising from MSN's further amendment of its ANDA filing with the FDA. On August 9, 2022, MSN filed its response to the complaint, alleging that the asserted claims of U.S. Patent No. 11,298,349 are invalid and not infringed and amended its challenges to U.S. Patents No. 11,091,439, 11,091,440 and 11,098,015 to allege that these patents are not enforceable based on equitable grounds. The two lawsuits comprising this litigation (collectively referred to as MSN II), numbered Civil Action Nos. 22-00228 and 22-00945, were consolidated in October 2022 and involve Exelixis patents that are different from those asserted in the MSN I litigation described above.

On June 21, 2022, pursuant to a stipulation between us and MSN, the Delaware District Court entered an order that (i) MSN's submission of its ANDA constitutes infringement of certain claims relating to U.S. Patents No. 11,091,439, 11,091,440 and 11,098,015, if those claims are not found to be invalid, and (ii) upon approval, MSN's commercial manufacture, use, sale or offer for sale within the U.S., and importation into the U.S., of MSN's proposed ANDA product prior to the expiration of U.S. Patents No. 11,091,439, 11,091,440 and 11,098,015 would also infringe certain claims of each patent, if those claims are not found to be invalid. In our MSN II complaints, we sought, among other relief, an order that the effective date of any FDA approval of MSN's ANDA would be a date no earlier than the expiration of all of U.S. Patents No. 11,091,439, 11,091,440, 11,098,015 and 11,298,349, the latest of which expires on February 10, 2032, and equitable relief enjoining MSN from infringing these patents. On September 28, 2023, the Delaware District Court granted the parties' stipulation of dismissal of MSN's equitable defenses and counterclaims. A bench trial occurred in October 2023, and on October 15, 2024, the Delaware District Court issued a ruling rejecting MSN's invalidity challenge to each of U.S. Patents No. 11,091,439, 11,091,440 and 11,098,015. The Delaware District Court also ruled that our U.S. Patent No. 11,298,349 is not invalid and that MSN's proposed ANDA product does not infringe this patent. In accordance with these rulings, the Delaware District Court entered final judgment on October 23, 2024, that, should the FDA ultimately approve MSN's ANDA, the effective date of any such approval of MSN's ANDA shall not be a date earlier than January 15, 2030, the expiration date of each of U.S. Patents No. 11,091,439, 11,091,440 and 11,098,015, subject to our potential additional regulatory exclusivity.

On November 22, 2024, MSN noticed an appeal to the Court of Appeals for the Federal Circuit and we noticed a cross-appeal on November 26, 2024. We are currently evaluating next steps with respect to this litigation.

In February 2025, we received another notice letter from MSN regarding its ANDA, requesting FDA approval to market a generic version of CABOMETYX tablets. MSN's notice letter included a Paragraph IV certification with respect to Orange Book-listed patent U.S. Patent No. 12,128,039 (low impurity), which expires in 2032. We intend to continue to vigorously defend our cabozantinib intellectual property estate.

Teva ANDA Litigation

In May 2021, we received notice letters regarding an ANDA submitted to the FDA by Teva Pharmaceutical Industries Limited, Teva Pharmaceuticals Development, Inc. and Teva Pharmaceuticals USA, Inc. (individually and collectively referred to as Teva), requesting approval to market a generic version of CABOMETYX tablets. Teva's notice letters included a Paragraph IV certification with respect to our U.S. Patents No. 9,724,342 (formulations), 10,034,873 (methods of treatment) and 10,039,757 (methods of treatment), which are listed in the Orange Book. Teva's notice letters did not provide a Paragraph IV certification against any additional CABOMETYX patents. On June 17, 2021, we filed a complaint in the Delaware District Court for patent infringement against Teva asserting infringement of U.S. Patents No. 9,724,342, 10,034,873 and 10,039,757 arising from Teva's ANDA filing with the FDA. On August 27, 2021, Teva filed its answer and counterclaims to the complaint, alleging that the asserted claims of U.S. Patents No. 9,724,342, 10,034,873 and 10,039,757 are invalid and not infringed. On September 17, 2021, we filed an answer to Teva's counterclaims. On July 29, 2022, we received notice from Teva that it had amended its ANDA to assert an additional Paragraph IV certification. As amended, Teva's ANDA now requests approval to market a generic version of CABOMETYX tablets prior to expiration of a previously-unasserted CABOMETYX patent that is now listed in the Orange Book: U.S. Patent No. 11,298,349 (pharmaceutical composition). On September 2, 2022, we filed a complaint in the Delaware District Court for patent infringement against Teva, asserting infringement of U.S. Patent No. 11,298,349 arising from Teva's amended ANDA filing with the FDA. We sought, among other relief, an order that the effective date of any FDA approval of Teva's ANDA be a date no earlier than the expiration of all of U.S. Patents No. 9,724,342, 10,034,873, 10,039,757 and 11,298,349, the latest of which expires on July 9, 2033, and equitable relief enjoining Teva from infringing these patents. On September 30, 2022, the parties filed a stipulation to consolidate the two lawsuits, numbered Civil Action Nos. 21-00871 and 22-01168, and to stay all proceedings, which was granted by the Delaware District Court on October 3, 2022. Following a similar order granted by the Delaware District Court on February 9, 2022 to stay all proceedings with respect to Civil Action No. 21-00871, this case remained administratively closed, and Civil Action No. 22-01168 was administratively closed on October 3, 2022. In July 2023, we entered into a settlement and license agreement with Teva (the Teva Settlement Agreement) to end these litigations. Pursuant to the terms of the Teva Settlement Agreement, we will grant Teva a license to market its generic version of CABOMETYX in the U.S. beginning on January 1, 2031, if approved by the FDA and subject to conditions and exceptions common to agreements of this type. On September 15, 2023, the parties filed a joint stipulation of dismissal with the Delaware District Court, and on September 19, 2023, the Delaware District Court granted the parties' stipulation and dismissed the case without prejudice.

Cipla ANDA Litigation

On February 6, 2023, we received a notice letter regarding an ANDA submitted to the FDA by Cipla, Ltd. and Cipla USA, Inc. (individually and collectively referred to as Cipla), including a Paragraph IV certification with respect to our U.S. Patents No. 8,877,776 (salt and polymorphic forms), 9,724,342 (formulations), 10,039,757 (methods of treatment), 11,091,439 (crystalline salt forms), 11,091,440 (pharmaceutical composition), 11,098,015 (methods of treatment) and 11,298,349 (pharmaceutical composition). Cipla's notice letter did not provide a Paragraph IV certification against any additional CABOMETYX patents. On March 16, 2023, we filed a complaint in the Delaware District Court for patent infringement against Cipla asserting infringement of U.S. Patents No. 8,877,776, 11,091,439, 11,091,440, 11,098,015 and 11,298,349 arising from Cipla's ANDA filing with the FDA. Cipla's ANDA requests approval to market a generic version of CABOMETYX tablets prior to the expiration of the aforementioned patents. We sought, among other relief, an order that the effective date of any FDA approval of Cipla's ANDA would be a date no earlier than the expiration of all of U.S. Patents No. 8,877,776, 11,091,439, 11,091,440, 11,098,015 and 11,298,349, the latest of which expires on February 10, 2032, and equitable relief enjoining Cipla from infringing these patents. On May 4, 2023, we filed, under seal, a stipulation and proposed order to stay all proceedings, and the Delaware District Court, in a sealed order on the same day, granted the proposed order and administratively closed the case. On May 5, 2023, the Delaware District Court issued a redacted version of the May 4, 2023 stipulation and proposed order. On March 27, 2024, we received notice from Cipla that it had amended its ANDA to assert additional Paragraph IV certifications. The ANDA now requests approval to market generic versions of CABOMETYX tablets with 20 mg and 40 mg dosage strengths (in addition to the 60 mg dosage strength contemplated by

Cipla's original ANDA) prior to expiration of U.S. Patents No. 8,877,776, 9,724,342, 10,039,757, 11,091,439, 11,091,440, 11,098,015 and 11,298,349. In May 2024, we entered into a settlement and license agreement (the Cipla Settlement Agreement) with Cipla to end these litigations. Pursuant to the terms of the Cipla Settlement Agreement, we granted Cipla a license to market its generic version of CABOMETYX in the U.S. beginning on January 1, 2031, if approved by the FDA and subject to conditions and exceptions common to agreements of this type. On July 8, 2024, the parties filed a joint stipulation of dismissal with the Delaware District Court, and on July 9, 2024, the Delaware District Court granted the parties' stipulation and dismissed the case without prejudice.

Sun ANDA Litigation

On September 17, 2024, we received a notice letter regarding an ANDA submitted to the FDA by Sun Pharmaceutical Industries Ltd. (Sun), requesting approval to market a generic version of CABOMETYX tablets. Sun's notice letter included a Paragraph IV certification with respect to our U.S. Patents No. 8,877,776 (salt and polymorphic forms), 9,724,342 (formulations), 10,034,873 (methods of treatment), 10,039,757 (methods of treatment), 11,091,439 (crystalline salt forms), 11,091,440 (pharmaceutical composition), 11,098,015 (methods of treatment) and 11,298,349 (pharmaceutical composition), which are listed in the Approved Drug Products with Therapeutic Equivalence Evaluations, also referred to as the Orange Book, for CABOMETYX. On October 30,2024 we filed a complaint in the United States District Court for the District of Delaware (the Delaware District Court) for patent infringement against Sun asserting infringement of U.S. Patent Nos. 8,877,776, 11,091,439, 11,091,440, and 11,098,015. On January 22, 2025, Sun filed its response to the complaint, alleging that the asserted claims of U.S. Patent No. 8,877,776, 11,091,439, 11,091,440, and 11,098,015 are invalid and not infringed. Sun also filed counterclaims that, inter alia, seek a declaratory judgment that Sun's ANDA would not infringe any valid and enforceable claim of U.S. Patent Nos. 8,877,776, 11,091,439, 11,091,440, 11,098,015, 9,724,342, 10,034,873, 10,039,757, and 11,298,349. We have not yet responded to Sun's counterclaims.

Other

On November 18, 2024, Azurity Pharmaceuticals, Inc. (Azurity) filed a petition seeking *inter partes* (IPR) review of U.S. Patent No. 11,298,349 at the United States Patent and Trademark Office. The proceeding was accorded a filing date of December 12, 2024 and our preliminary response is due March 12, 2025. On January 9, 2025, Azurity filed a petition seeking IPR review of U.S. Patent No. 12,128,039 at the United States Patent and Trademark Office. The proceeding has not yet been accorded a filing date.

The sale of any generic version of CABOMETYX earlier than its patent expiration could significantly decrease our revenues derived from the U.S. sales of CABOMETYX and thereby materially harm our business, financial condition and results of operations. It is not possible at this time to determine the likelihood of an unfavorable outcome or estimate of the amount or range of any potential loss.

We may also from time to time become a party or subject to various other legal proceedings and claims, either asserted or unasserted, which arise in the ordinary course of business. Some of these proceedings have involved, and may involve in the future, claims that are subject to substantial uncertainties and unascertainable damages.

NOTE 13. RESTRUCTURING

In January 2024, our Board of Directors authorized, and we implemented, a corporate restructuring plan (the 2024 Restructuring Plan) to reduce our workforce and rebalance our cost structure in alignment with our strategic priorities. Restructuring expenses incurred under the 2024 Restructuring Plan include: severance and employee-related costs; impairment of long-lived assets; and contract termination and other exit costs. The total restructuring costs, incurred during the year ended December 31, 2024, associated with the 2024 Restructuring Plan were $33.7 million and were recorded to the restructuring expense line item within our Consolidated Statements of Income as they were incurred through the end of the plan. We incurred the majority of the costs related to the 2024 Restructuring Plan during the first quarter of 2024.

In connection with the 2024 Restructuring Plan, we exited two leases in the Greater Philadelphia area and the right-of-use assets, related leasehold improvements and certain other long-lived assets were remeasured and recorded at fair value, see "Note 12. Commitments and Contingencies" for additional information.

The restructuring activities and balances as of and for the year ended December 31, 2024, were as follows (in thousands):

	Accrued at December 31, 2023	Year Ended December 31, 2024				Accrued at December 31, 2024[3]	Total Costs Incurred to Date	Total Expected Plan Costs
		Initial Costs	Adj. to Costs[2]	Non-cash charges	Cash Payments			
Severance and employee-related costs	$ —	$ 15,656	$ 69	$ —	$ (15,469)	$ 256	$ 15,725	$ 15,725
Contract termination and other exit costs[1]	—	5,220	(4)	—	(5,216)	—	5,216	5,216
Impairment of long-lived assets	—	12,318	401	(12,719)	—	—	12,719	12,719
Total restructuring	$ —	$ 33,194	$ 466	$ (12,719)	$ (20,685)	$ 256	$ 33,660	$ 33,660

[1] Contract termination costs consist of accruals for costs incurred without future economic benefit, and other exit costs expensed as incurred.

[2] Adjustments to costs consist of changes in estimates whereby increases and decreases in costs were recorded to operating expenses in the period of adjustments.

[3] As of December 31, 2024, all restructuring liabilities have been recorded in accrued compensation and benefits in the accompanying Consolidated Balance Sheets.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

Not applicable.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures. Based on the evaluation of our disclosure controls and procedures (as defined under Rules 13a-15(e) or 15d-15(e) under the Securities Exchange Act of 1934, as amended) required by Rules 13a-15(b) or 15d-15(b) under the Securities Exchange Act of 1934, as amended, our Chief Executive Officer and our Chief Financial Officer have concluded that as of the end of the period covered by this report, our disclosure controls and procedures were effective.

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 an organization 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. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management's Report on Internal Control Over Financial Reporting. Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15(d)-15(f). Our internal control over financial reporting is a process designed under the supervision of our principal executive and principal financial officers to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external reporting purposes in accordance with U.S. generally accepted accounting principles.

As of the end of our 2024 fiscal year, management conducted an assessment of the effectiveness of our internal control over financial reporting based on the framework established in the original *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (COSO). Based on this assessment, management has determined that our internal control over financial reporting as of January 3, 2025 was effective. There were no material weaknesses in internal control over financial reporting identified by management.

The independent registered public accounting firm Ernst & Young LLP has issued an audit report on our internal control over financial reporting, which is included on the following page.

Changes in Internal Control Over Financial Reporting. There were no changes in our internal control over financial reporting that occurred during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Exelixis, Inc.

Opinion on Internal Control Over Financial Reporting

We have audited Exelixis, Inc.'s internal control over financial reporting as of January 3, 2025, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Exelixis, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of January 3, 2025, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of January 3, 2025 and December 29, 2023, the related consolidated statements of income, comprehensive income, stockholders' equity and cash flows for each of the three years in the period ended January 3, 2025, and the related notes and our report dated February 11, 2025 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

San Mateo, California
February 11, 2025

Item 9B. Other Information.

Jack L Wyszomierski, a member of our Board of Directors, entered into a pre-arranged stock trading plan on November 29, 2024. Mr. Wyszomierski's trading plan provides for the sale of up to 23,409 shares of our common stock (including shares obtained from the exercise of vested stock options covered by the trading plan) between February 28, 2025 and June 13, 2025. This trading plan is intended to satisfy the affirmative defense of Rule 10b5-1(c) under the Exchange Act and Exelixis' policies regarding transactions in Exelixis securities.

S. Gail Eckhardt, a member of our Board of Directors, entered into a pre-arranged stock trading plan on October 30, 2024. Ms. Eckhardt's trading plan provides for the sale of up to 30,406 shares of our common stock (including shares obtained from the exercise of vested stock options covered by the trading plan) between February 14, 2025 and September 30, 2025. This trading plan is intended to satisfy the affirmative defense of Rule 10b5-1(c) under the Exchange Act and Exelixis' policies regarding transactions in Exelixis securities.

During the three months ended December 31, 2024, no other directors or Section 16 officers of the Company adopted or terminated any "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408 of Regulation S-K.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item relating to our directors and nominees, including information with respect to our audit committee, audit committee financial experts and procedures by which stockholders may recommend nominees to our Board of Directors, is incorporated by reference to the section entitled "Proposal 1 – Election of Directors" appearing in our Proxy Statement for our 2025 Annual Meeting of Stockholders to be filed with the SEC within 120 days after January 3, 2025, which we refer to as our 2025 Proxy Statement. The information required by this item regarding our executive officers is incorporated by reference to the section entitled "Information about our Executive Officers" appearing in our 2025 Proxy Statement. The information, if any, required by this item regarding compliance with Section 16(a) of the Securities Exchange Act of 1934, as amended, is incorporated by reference to the section entitled "Delinquent Section 16(a) Reports" appearing in our 2025 Proxy Statement. The information required by this item relating to our insider trading policies and procedures is incorporated by reference to the section entitled "Corporate Governance—Insider Trading Policies and Procedures" appearing in our 2025 proxy statement.

Code of Ethics

We have adopted a Corporate Code of Conduct that applies to all of our directors, officers and employees, including our principal executive officer, principal financial officer and principal accounting officer. The Corporate Code of Conduct is posted on our website at www.exelixis.com under the caption "Investors & News—Corporate Governance."

We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding an amendment to, or waiver from, a provision of this Corporate Code of Conduct by posting such information on our website, at the address and location specified above and, to the extent required by the listing standards of the Nasdaq Stock Market, by filing a Current Report on Form 8-K with the SEC, disclosing such information.

Item 11. Executive Compensation.

The information required by this item is incorporated by reference to the sections entitled "Compensation of Executive Officers," "Compensation of Directors," "Compensation Committee Interlocks and Insider Participation" and "Compensation Committee Report" appearing in our 2025 Proxy Statement.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item relating to security ownership of certain beneficial owners and management is incorporated by reference to the section entitled "Security Ownership of Certain Beneficial Owners and Management" appearing in our 2025 Proxy Statement.

Equity Compensation Plan Information

The following table provides certain information about our common stock that may be issued upon the exercise of stock options and other rights under all of our existing equity compensation plans as of December 31, 2024, which consists of our 2000 Employee Stock Purchase Plan (as amended and restated, the Amended ESPP), and our 2017 Equity Incentive Plan (as amended and restated, the 2017 Plan) (in thousands, except per share amounts):

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity compensation plans approved by stockholders [1]	18,005	$ 5.29 [2]	35,595
Total	18,005	$ 5.29	35,595

[1] Equity plans approved by our stockholders include the 2017 Plan and the Amended ESPP. As of December 31, 2024, a total of 7.0 million shares of our common stock remained available for issuance under the Amended ESPP, and up to a maximum of 0.8 million shares of our common stock may be purchased in the current purchase period. The shares issuable pursuant to our Amended ESPP are not included in the number of shares to be issued pursuant to rights outstanding and the weighted-average exercise price of such rights as of December 31, 2024, as those numbers are not known.

[2] The weighted-average exercise price takes into account the shares subject to outstanding restricted stock units (RSUs), including such awards with performance and market conditions, which have no exercise price. The weighted-average exercise price, excluding such outstanding RSUs, is $20.64.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item is incorporated by reference to the sections entitled "Certain Relationships and Related Party Transactions" and "Proposal 1 – Election of Directors" appearing in our 2025 Proxy Statement.

Item 14. Principal Accountant Fees and Services.

The information required by this item is incorporated by reference to the section entitled "Proposal 2 – Ratification of Selection of Independent Registered Public Accounting Firm" appearing in our 2025 Proxy Statement.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) The following documents are being filed as part of this report:

(1) The following financial statements and the Report of Independent Registered Public Accounting Firm are included in Part II, Item 8:

(2) All financial statement schedules are omitted because the information is inapplicable or presented in the Notes to Consolidated Financial Statements.

(3) The following Exhibits are filed as part of this report.

		Incorporation by Reference				
Exhibit Number	Exhibit Description	Form	File Number	Exhibit/ Appendix Reference	Filing Date	Filed Herewith
3.1	Restated Certificate of Incorporation of Exelixis, Inc.	10-Q	000-30235	3.1	8/5/2021	
3.2	Certificate of Change of Registered Agent and/or Registered Office	10-Q	000-30235	3.2	4/30/2024	
3.3	Amended and Restated Bylaws of Exelixis, Inc.	8-K	000-30235	3.1	12/20/2023	
4.1	Specimen Common Stock Certificate.	10-Q	000-30235	4.1	8/5/2021	
4.2	Description of the Common Stock of Exelixis, Inc. Registered Pursuant to Section 12 of the Securities Exchange Act of 1934, as amended	10-K	000-30235	4.2	2/18/2022	
10.1†	Form of Indemnification Agreement	10-K	000-30235	10.1	2/18/2022	
10.2†	Exelixis, Inc. 2000 Employee Stock Purchase Plan	10-Q	000-30235	10.1	8/6/2024	
10.3†	Exelixis, Inc. 2014 Equity Incentive Plan	10-Q	000-30235	10.1	8/6/2020	
10.4†	Form of Stock Option Agreement under the Exelixis, Inc. 2014 Equity Incentive Plan	10-Q	000-30235	10.2	7/31/2014	
10.5†	Form of Stock Option Agreement (Non-Employee Director) under the Exelixis, Inc. 2014 Equity Incentive Plan	10-Q	000-30235	10.4	7/31/2014	
10.6†	Form of Restricted Stock Unit Agreement under the Exelixis, Inc. 2014 Equity Incentive Plan	10-Q	000-30235	10.5	7/31/2014	
10.7†	Exelixis, Inc. 2016 Inducement Award Plan	10-Q	000-30235	10.2	8/6/2020	
10.8†	Exelixis, Inc. 2017 Equity Incentive Plan	10-Q	000-30235	10.1	8/9/2022	

Exhibit Number	Exhibit Description	Incorporation by Reference				Filed Herewith
		Form	File Number	Exhibit/ Appendix Reference	Filing Date	
10.9†	Form of Stock Option Agreement under the Exelixis, Inc. 2017 Equity Incentive Plan	10-K	000-30235	10.11	2/11/2021	
10.10†	Form of Stock Option Agreement (Non-Employee Director) under the Exelixis, Inc. 2017 Equity Incentive Plan	10-K	000-30235	10.22	2/26/2018	
10.11†	Form of Restricted Stock Unit Agreement under the Exelixis, Inc. 2017 Equity Incentive Plan	10-Q	000-30235	10.5	8/6/2020	
10.12†	Form of Restricted Stock Unit Agreement (Non-Employee Director) under the Exelixis, Inc. 2017 Equity Incentive Plan	10-Q	000-30235	10.6	8/6/2020	
10.13†	Non-Employee Director Equity Compensation Policy	10-Q	000-30235	10.4	5/5/2020	
10.14†	Offer Letter Agreement, dated February 3, 2000, between Exelixis, Inc. and Michael Morrissey, Ph.D.	10-Q	000-30235	10.43	8/5/2004	
10.15†	Offer Letter Agreement, dated July 1, 2015, between Exelixis, Inc. and Christopher Senner	10-Q	000-30235	10.5	11/10/2015	
10.16†	Offer Letter Agreement, dated August 27, 2023, between Exelixis, Inc. and Amy C. Peterson	10-K	000-30235	10.18	2/6/2024	
10.17†	Offer Letter Agreement, dated February 10, 2014, between Exelixis, Inc. and Jeffrey J. Hessekiel.	10-Q	000-30235	10.4	5/1/2014	
10.18†	Terms of Employment Offer, dated December 15, 2022, for Dana T. Aftab, Ph.D.	10-K	000-30235	10.20	2/7/2023	
10.19†	Offer Letter Agreement, dated August 19, 2010, between Exelixis, Inc. and Patrick J. Haley	10-K	000-30235	10.26	2/27/2017	
10.20†	Annual Cash Bonus Compensation Plan for Executives	8-K	000-30235	10.1	2/16/2018	
10.21†	Cash Compensation Information for Non-Employee Directors.	10-K	000-30235	10.23	2/6/2024	
10.22†	Exelixis, Inc. Change in Control and Severance Benefit Plan, as amended and restated.	10-K	000-30235	10.24	2/6/2024	
10.23	Lease Agreement dated May 2, 2017, between Ascentris 105, LLC and Exelixis, Inc.	10-Q	000-30235	10.1	8/2/2017	
10.24	First Amendment dated October 16, 2017, to Lease Agreement dated May 2, 2017, between Ascentris 105, LLC and Exelixis, Inc.	10-K	000-30235	10.39	2/26/2018	
10.25	Second Amendment dated June 13, 2018, to Lease Agreement dated May 2, 2017, between Ascentris 105, LLC and Exelixis, Inc.	10-Q	000-30235	10.2	8/1/2018	

Exhibit Number	Exhibit Description	Incorporation by Reference				Filed Herewith
		Form	File Number	Exhibit/ Appendix Reference	Filing Date	
10.26	Third Amendment dated April 1, 2019, to Lease Agreement dated May 2, 2017, between Ascentris 105, LLC and Exelixis, Inc.	8-K	000-30235	10.1	4/5/2019	
10.27	Fourth Amendment dated August 30, 2019, to Lease Agreement dated May 2, 2017, between Hillwood Enterprises, L.P. (as successor in interest to Ascentris 105, LLC) and Exelixis, Inc.	10-Q	000-30235	10.3	10/30/2019	
10.28	Fifth Amendment dated January 16, 2020, to Lease Agreement dated May 2, 2017, between Waterfront EDP, LLC (as successor in interest to Hillwood Enterprises, L.P.) and Exelixis, Inc.	10-K	000-30235	10.37	2/25/2020	
10.29	Sixth Amendment dated December 11, 2020, to Lease Agreement dated May 2, 2017, between SCG Harbor Bay Parkway Phase I, LLC (as successor in interest to Waterfront EDP, LLC) and Exelixis, Inc.	10-K	000-30235	10.32	2/11/2021	
10.30	Seventh Amendment dated May 16, 2022, to Lease Agreement dated May 2, 2017, between SCG Harbor Bay Parkway Phase I, LLC and Exelixis, Inc.	10-Q	000-30235	10.3	8/9/2022	
10.31	Lease Agreement dated October 25, 2019, between Ernst Development Partners, Inc. and Exelixis, Inc.	10-Q	000-30235	10.2	10/30/2019	
10.32	First Amendment dated January 16, 2020, to Lease Agreement dated October 25, 2019, between Alameda BTS EDP, LLC (as successor in interest to Ernst Development Partners, Inc.) and Exelixis, Inc.	10-K	000-30235	10.39	2/25/2020	
10.33**	Collaboration and License Agreement dated February 29, 2016, by and between Exelixis, Inc. and Ipsen Pharma SAS	10-Q	000-30235	10.1	5/6/2021	
10.34**	First Amendment dated December 20, 2016, to the Collaboration and License Agreement dated February 29, 2016, by and between Exelixis, Inc. and Ipsen Pharma SAS	10-Q	000-30235	10.2	5/6/2021	
10.35**	Second Amendment dated September 14, 2017, to the Collaboration and License Agreement dated February 29, 2016, by and between Exelixis, Inc. and Ipsen Pharma SAS	10-Q	000-30235	10.3	5/6/2021	
10.36**	Third Amendment dated October 26, 2017, to the Collaboration and License Agreement dated February 29, 2016, by and between Exelixis, Inc. and Ipsen Pharma SAS	10-Q	000-30235	10.4	5/6/2021	

Exhibit Number	Exhibit Description	Incorporation by Reference				Filed Herewith
		Form	File Number	Exhibit/ Appendix Reference	Filing Date	
10.37**	Fourth Amendment dated October 11, 2022, to the Collaboration and License Agreement dated February 29, 2016, by and between Exelixis, Inc. and Ipsen Pharma SAS	10-K	000-30235	10.40	2/7/2023	
10.38**	Fifth Amendment dated August 24, 2023, to the Collaboration and License Agreement dated February 29, 2016, by and between Exelixis, Inc. and Ipsen Pharma SAS	10-Q	000-30235	10.1	11/1/2023	
10.39**	Supply Agreement dated February 29, 2016, by and between Exelixis, Inc. and Ipsen Pharma SAS	10-Q	000-30235	10.5	5/6/2021	
10.40**	First Amendment dated October 26, 2017, to the Supply Agreement dated February 29, 2016, by and between Exelixis, Inc. and Ipsen Pharma SAS	10-Q	000-30235	10.6	5/6/2021	
10.41**	Second Amendment dated May 17, 2019, to the Supply Agreement dated February 29, 2016, by and between Exelixis, Inc. and Ipsen Pharma SAS	10-Q	000-30235	10.2	7/31/2019	
10.42**	Third Amendment dated December 10, 2021, to the Supply Agreement dated February 29, 2016, by and between Exelixis, Inc. and Ipsen Pharma SAS	10-K	000-30235	10.42	2/18/2022	
10.43**	Collaboration and License Agreement dated January 30, 2017, by and between Exelixis, Inc. and Takeda Pharmaceutical Company Limited	10-Q	000-30235	10.1	5/10/2022	
10.44*	First Amendment dated March 22, 2018, to the Collaboration and License Agreement dated January 30, 2017, by and between Exelixis, Inc. and Takeda Pharmaceutical Company Limited	10-Q	000-30235	10.1	8/1/2018	
10.45**	Second Amendment dated May 7, 2019, to the Collaboration and License Agreement dated January 30, 2017, by and between Exelixis, Inc. and Takeda Pharmaceutical Company Limited	10-Q	000-30235	10.2	5/10/2022	
10.46**	Third Amendment dated September 3, 2020, to the Collaboration and License Agreement dated January 30, 2017, by and between Exelixis, Inc. and Takeda Pharmaceutical Company Limited	10-Q	000-30235	10.1	11/5/2020	
10.47**	Joint Clinical Research Agreement dated December 18, 2019, by and between Exelixis, Inc. and F. Hoffmann-La Roche Ltd	10-K	000-30235	10.62	2/25/2020	
19.1	Exelixis, Inc. Insider Trading Policy					X
19.2	Exelixis, Inc. Rule 10b5-1 Trading Plan Policy					X
21.1	Subsidiaries of Exelixis, Inc.					X
23.1	Consent of Independent Registered Public Accounting Firm					X

Exhibit Number	Exhibit Description	Incorporation by Reference				Filed Herewith
		Form	File Number	Exhibit/ Appendix Reference	Filing Date	
24.1	Power of Attorney (contained on signature page)					X
31.1	Certification of Principal Executive Officer Pursuant to Exchange Act Rules 13a-14(a) and Rule 15d-14(a)					X
31.2	Certification of Principal Financial Officer Pursuant to Exchange Act Rules 13a-14(a) and Rule 15d-14(a)					X
32.1‡	Certifications of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350					X
97.1†	Exelixis, Inc. Policy for Recoupment of Variable Compensation, amended and restated	10-K	000-30235	97.1	2/6/2024	
101.INS	XBRL Instance Document	The XBRL 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					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					X
104	Cover Page Interactive Data File	Formatted as Inline XBRL and contained in Exhibit 101.				

† Management contract or compensatory plan.

* Confidential treatment granted for certain portions of this exhibit.

** Portions of this exhibit have been omitted as being immaterial and would be competitively harmful if publicly disclosed.

‡ This certification accompanies this Annual Report on Form 10-K, 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 this Annual Report on Form 10-K), irrespective of any general incorporation language contained in such filing.

ITEM 16. Form 10-K Summary.

None provided.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized

EXELIXIS, INC.

February 11, 2025	By:	/s/ MICHAEL M. MORRISSEY
Date		**Michael M. Morrissey, Ph.D.**
		President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints **MICHAEL M. MORRISSEY**, **CHRISTOPHER J. SENNER** and **JEFFREY J. HESSEKIEL** and each or any one of them, his or her true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his or her substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signatures	Title	Date
/s/ MICHAEL M. MORRISSEY **Michael M. Morrissey, Ph.D.**	Director, President and Chief Executive Officer (Principal Executive Officer)	February 11, 2025
/s/ CHRISTOPHER J. SENNER **Christopher J. Senner**	Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	February 11, 2025
/s/ STELIOS PAPADOPOULOS **Stelios Papadopoulos, Ph.D.**	Chairman of the Board	February 11, 2025
/s/ MARY C. BECKERLE **Mary C. Beckerle, Ph.D.**	Director	February 11, 2025
/s/ S. GAIL ECKHARDT **S. Gail Eckhardt, M.D.**	Director	February 11, 2025
/s/ MARIA C. FREIRE **Maria C. Freire, Ph.D.**	Director	February 11, 2025

Signatures	Title	Date
/s/ TOMAS J. HEYMAN **Tomas J. Heyman**	Director	February 11, 2025
/s/ DAVID E. JOHNSON **David E. Johnson**	Director	February 11, 2025
/s/ ROBERT L. OLIVER **Robert L. Oliver, Jr.**	Director	February 11, 2025
/s/ GEORGE POSTE **George Poste, DVM, Ph.D., FRS**	Director	February 11, 2025
/s/ JULIE A. SMITH **Julie A. Smith**	Director	February 11, 2025
/s/ JACK L. WYSZOMIERSKI **Jack L. Wyszomierski**	Director	February 11, 2025

Corporate Information

Corporate Headquarters

Exelixis, Inc.
1851 Harbor Bay Parkway
Alameda, CA 94502
Phone: 650.837.7000
Fax: 650.837.8300

Website
www.exelixis.com

X
@ExelixisInc

Facebook
www.facebook.com/ExelixisInc

LinkedIn
www.linkedin.com/company/Exelixis

Transfer Agent

For any inquiries regarding transfer requirements, lost stock certificates and address changes, please contact our transfer agent.

Computershare
P.O. Box 43006
Providence, RI 02940-3006

Private Couriers/Registered Mail:
Computershare Investor Services
150 Royall Street, Suite 101
Canton, MA 02021

Website Address:
www.computershare.com/investor

Shareholder Online Inquiries:
https://www-us.computershare.com/investor/contact

Annual Meeting

To be held virtually on Wednesday, May 28, 2025, at 9:00 a.m. PT.

View the meeting, submit questions and vote online at www.virtualshareholdermeeting.com/EXEL2025.

Please see our Proxy Statement for the 2025 Annual Meeting for details on how to vote your shares or attend the meeting.

Independent Auditors

Ernst & Young LLP
Redwood City, CA

Investor Relations / Form 10-K

Inquiries and requests for information, including copies of the Exelixis Annual Report on Form 10-K provided free of charge, may be directed to the company's Investor Relations Department by phone (650.837.7000), email (IR@exelixis.com) or via our website (exelixis.com).

Stock Information

The common stock of the company has traded on the Nasdaq Global Select Market under the symbol "EXEL" since April 11, 2000.

Board of Directors

Stelios Papadopoulos, Ph.D.
Co-Founder and Chair of the Board, Exelixis, Inc.

Mary C. Beckerle, Ph.D.
Chief Executive Officer, Huntsman Cancer Institute and Associate Vice President for Cancer Affairs and Distinguished Professor of Biological and Oncological Sciences, University of Utah

S. Gail Eckhardt, M.D.
Associate Director of Translational Research, Dan L. Duncan Comprehensive Cancer Center, and Professor and Associate Dean of Experimental Therapeutics, Baylor College of Medicine

Maria C. Freire, Ph.D.
Chair of the Nominating and Corporate Governance Committee, Exelixis, Inc.; Former President, Executive Director and Director, Foundation for the National Institutes of Health

Tomas J. Heyman
Chair of the Risk Committee, Exelixis, Inc.; Operating Partner, Bioqube Ventures; Former President, Johnson & Johnson's Corporate Venture Capital Group

David E. Johnson
Managing Partner and Chief Investment Officer, Caligan Partners LP

Michael M. Morrissey, Ph.D.
President and Chief Executive Officer, Exelixis, Inc.

Robert L. Oliver, Jr.
Executive Advisor to CELLIX Biosciences and Hyalo Technologies LLC; Former President and Chief Executive Officer, Otsuka America Pharmaceutical, Inc.

George Poste, DVM, Ph.D., FRS
Chair of the Research & Development Committee, Exelixis, Inc.; Chief Scientist, Complex Adaptive Systems Initiative and Regents' Professor and Del E. Webb Professor of Health Innovation, Arizona State University; Chief Executive Officer, Health Technology Networks

Julie Anne Smith
Chair of the Compensation Committee, Exelixis, Inc.; Former Chief Executive Officer, Nuvig Therapeutics, Inc.

Jack L. Wyszomierski
Chair of the Audit Committee, Exelixis, Inc.; Former Executive Vice President and Chief Financial Officer, VWR International, LLC

Management Team

Michael M. Morrissey, Ph.D.
President and Chief Executive Officer

Christopher J. Senner
Executive Vice President and Chief Financial Officer

Amy C. Peterson, M.D.
Executive Vice President, Product Development and Medical Affairs and Chief Medical Officer

Dana T. Aftab, Ph.D.
Executive Vice President, Discovery and Translational Research and Chief Scientific Officer

P.J. Haley, MBA
Executive Vice President, Commercial

Jeffrey J. Hessekiel, J.D.
Executive Vice President and General Counsel

Susan T. Hubbard
Executive Vice President, Public Affairs and Investor Relations

This Annual Report contains forward-looking statements, including, without limitation, statements related to: Exelixis' business plans and commitments, including key clinical development, label expansion and pipeline-building milestones expected for 2025 and beyond; Exelixis' optimism for the cabozantinib franchise's revenue outlook through 2030 and the continued growth of its base business with CABOMETYX; Exelixis' aim to establish CABOMETYX as the small molecule market leader in NET; Exelixis' belief in the clinical, therapeutic and commercial potential of zanzalintinib, as well as Exelixis' expectation that zanzalintinib will take center stage in 2025; anticipated zanzalintinib pivotal data milestones, including with respect to the STELLAR-303, STELLAR-304, and STELLAR-305 trials; Exelixis' anticipated timing for initiation of pivotal studies planned for 2025, including STELLAR-311; Exelixis' expectations with respect to its clinical development collaboration with Merck; Exelixis' projections with respect to U.S. net product revenues for zanzalintinib; the therapeutic potential of, and data milestones with respect to Exelixis' product candidates, including XL309, XB010, and XB628; statements related to Exelixis' intended share repurchases and repurchase timeframe; Exelixis' plans with respect to its advancement of multiple internal phase 1 programs with best- and/or first-in-class potential and the potential of its preclinical programs to be the subject of additional future IND filings; Exelixis' scientific pursuit to create transformational treatments that give more patients hope for the future; and other statements that are not historical facts.

Any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements and are based upon Exelixis' current plans, assumptions, beliefs, expectations, estimates and projections. Forward-looking statements involve risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in the forward-looking statements as a result of these risks and uncertainties, which include, without limitation: the degree of market acceptance of CABOMETYX and other Exelixis products in the indications for which they are approved and in the territories where they are approved, and Exelixis and its partners' ability to obtain or maintain coverage and reimbursement for these products; the effectiveness of CABOMETYX and other Exelixis products in comparison to competing products; the level of costs associated with Exelixis' commercialization, research and development, in-licensing or acquisition of product candidates, and other activities; Exelixis' ability to maintain and scale adequate sales, marketing, market access and product distribution capabilities for its products or to enter into and maintain agreements with third parties to do so; the availability of data at the referenced times; the potential failure of cabozantinib, zanzalintinib and other Exelixis product candidates, both alone and in combination with other therapies, to demonstrate safety and/or efficacy in future clinical testing; uncertainties inherent in the drug discovery and product development process; Exelixis' dependence on its relationships with its collaboration partners, including their pursuit of regulatory approvals for partnered compounds in new indications, their adherence to their obligations under relevant collaboration agreements and the level of their investment in the resources necessary to complete clinical trials or successfully commercialize partnered compounds in the territories where they are approved; complexities and the unpredictability of regulatory review and approval processes in the U.S. and elsewhere; Exelixis' continuing compliance with applicable legal and regulatory requirements; unexpected concerns that may arise as a result of the occurrence of adverse safety events or additional data analyses of clinical trials evaluating cabozantinib, zanzalintinib and other Exelixis products; Exelixis' dependence on third-party vendors for the development, manufacture and supply of its products and product candidates; Exelixis' ability to protect its intellectual property rights; market competition, including the potential for competitors to obtain approval for generic versions of Exelixis' marketed products; changes in economic and business conditions; and other factors discussed under the caption "Risk Factors" in Exelixis' Form 10-K filed with the SEC on February 11, 2025, which is part of this Annual Report, and subsequent Quarterly Reports on Form 10-Q, and in Exelixis' future filings with the SEC. All forward-looking statements in this Annual Report are based on information available to Exelixis as of the date of this Annual Report, and Exelixis undertakes no obligation to update or revise any forward-looking statements contained herein, except as required by law.

Exelixis, Inc.
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