## STEWART & STEVENSON SERVICES INC Form DEFR14A April 29, 2002

(1) Amount Previously Paid:

## SCHEDULE 14A INFORMATION

		Proxy Statement Pursuant to Section 14(a) of the Securities Exchange Act of 1934 (Amendment No. )						
		ed by the Registrant / / ed by a party other than the Registrant / /						
	/ / / / /X/ / /	Preliminary Proxy Statement CONFIDENTIAL, FOR USE OF THE COMMISSION ONLY (AS PERMITTED BY RULE 14a-6(e)(2)) Definitive Proxy Statement Definitive Additional Materials Soliciting Material Pursuant to Section 240.14a-12						
		STEWART & STEVENSON SERVICES, INC.						
		(Name of Registrant as Specified In Its Charter)						
	(Nar	ne of Person(s) Filing Proxy Statement, if other than the Registrant)						
Payr	nent	of Filing Fee (Check the appropriate box):						
/X/	No	fee required.						
/ /	/ Fee computed on table below per Exchange Act Rules $14a-6(i)(4)$ and $0-11$ .							
	(1)	Title of each class of securities to which transaction applies:						
	(2)	Aggregate number of securities to which transaction applies:						
	(3)	Per unit price or other underlying value of transaction computed pursuant to Exchange Act Rule 0-11 (set forth the amount on which the filing fee is calculated and state how it was determined):						
	(4)	Proposed maximum aggregate value of transaction:						
	(5)	Total fee paid:						
/ /	Fee	paid previously with preliminary materials.						
/ /	0-13 prev	ck box if any part of the fee is offset as provided by Exchange Act Rule I(a)(2) and identify the filing for which the offsetting fee was paid viously. Identify the previous filing by registration statement number, the Form or Schedule and the date of its filing.						

(2)	Form,	Schedule	or	Registration	Statement	No.:
(3)	Filing	g Party:				
(4)	Date I	Filed:				

STEWART & STEVENSON SERVICES, INC.
2707 NORTH LOOP WEST
P.O. BOX 1637
HOUSTON, TEXAS 77251-1637

NOTICE OF ANNUAL MEETING OF SHAREHOLDERS TO BE HELD JUNE 11, 2002

Dear Shareholder:

The Annual Meeting of Shareholders of Stewart & Stevenson Services, Inc. (the "Company") will be held at 10:00 a.m. on Tuesday, June 11, 2002, in the Doubletree Hotel, 2001 Post Oak Blvd., Houston, Texas, for the following purposes:

- 1. Election of four directors to the Board of Directors.
- 2. Approval of the Amended and Restated 1996 Director Stock Plan.
- Ratification of Ernst & Young LLP as the Company's independent auditors for the fiscal year ending January 31, 2003.

Only record holders of our Common Stock at the close of business on April 24, 2002 will be entitled to vote at the meeting or any adjournment thereof.

IT IS IMPORTANT THAT YOUR SHARES BE REPRESENTED AT THE MEETING. EVEN IF YOU PLAN TO ATTEND, WE URGE YOU TO COMPLETE AND SIGN THE PROXY CARD AND RETURN IT IN THE POSTAGE PAID ENVELOPE ENCLOSED IN THIS PACKAGE. The giving of such proxy does not affect your right to vote in person if you attend this meeting. The prompt return of your signed proxy will aid the Company in reducing the expense of additional proxy solicitation.

BY ORDER OF THE BOARD OF DIRECTORS

/s/ CARL B. KING CARL B. KING

MAY 3, 2002 SENIOR VICE PRESIDENT, SECRETARY AND GENERAL COUNSEL

YOUR VOTE IS IMPORTANT. PLEASE DATE, SIGN AND PROMPTLY RETURN YOUR PROXY SO THAT YOUR SHARES MAY BE VOTED IN ACCORDANCE WITH YOUR WISHES. THE GIVING OF SUCH PROXY DOES NOT AFFECT YOUR RIGHT TO VOTE IN PERSON IN THE EVENT YOU ATTEND THE

MEETING. YOUR PROXY MAY BE REVOKED AT ANY TIME BEFORE IT IS VOTED.

STEWART & STEVENSON SERVICES, INC.
2707 NORTH LOOP WEST
P.O. BOX 1637
HOUSTON, TEXAS 77251-1637

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PROXY STATEMENT FOR ANNUAL MEETING OF SHAREHOLDERS JUNE 11, 2002, AND ADJOURNMENTS

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APPROXIMATE DATE PROXY MATERIAL FIRST SENT TO SHAREHOLDERS:
MAY 3, 2002

SOLICITATION, VOTING AND REVOCABILITY OF PROXIES

The proxy furnished herewith, for use only at the Annual Meeting of Shareholders to be held at 10:00 a.m. on Tuesday, June 11, 2002, in the Doubletree Hotel, 2001 Post Oak Blvd., Houston, Texas, and any and all adjournments thereof, is solicited by the Board of Directors of Stewart & Stevenson Services, Inc. (the "Company"). Such solicitation is being made by mail and may also be made in person or by telephone by officers, directors and regular employees of the Company, and arrangements may be made with brokerage houses or other custodians, nominees and fiduciaries to send proxy material to their principals. In addition, the Company has retained Morrow & Co., Inc., a professional proxy solicitation firm, to assist in the solicitation of proxies. The Company has agreed to reimburse Morrow & Co., Inc. for expenses incurred in connection with the solicitation and to pay a solicitation fee of approximately \$4,000. The Company will pay all expenses incurred in this solicitation of proxies.

As of the date of these proxy materials, the Board of Directors is aware of the following matters that will be considered at the meeting:

- The election of four directors to the Board of Directors of the Company.
- 2. The approval of the Amended and Restated 1996 Director Stock Plan.
- 3. The ratification of Ernst & Young LLP as the Company's independent auditors for the fiscal year ending January 31, 2003.

The presence of the holders of a majority of the issued and outstanding shares of Common Stock entitled to vote, either in person or represented by proxy, is necessary to constitute a quorum for the transaction of business at the Annual Meeting. Proxies that withhold authority to vote for a nominee or abstain from voting on any matter are counted for the purpose of determining whether a quorum is present. Broker non-votes, which may occur when a broker or nominee has not received timely voting instructions on certain proposals, are not counted for the purpose of determining whether a quorum is present. If there are not

sufficient shares represented at the meeting to constitute a quorum, the meeting may be adjourned until a specified future date to allow the solicitation of additional proxies.

Directors are elected by a plurality of the votes cast at the meeting. The four nominees that receive the greatest number of votes will be elected even though the number of votes received may be less than a majority of the shares represented in person or by proxy at the meeting. Proxies that withhold authority to vote for a nominee and broker non-votes will not prevent the election of such nominee if other shareholders vote for such a nominee.

The approval of the Amended and Restated 1996 Director Stock Plan requires the affirmative vote of a majority of the shares represented in person or by proxy at the meeting. Proxies that abstain from voting on this proposal have the same effect as a vote against this proposal. Broker non-votes will not have any effect on this proposal.

The ratification of Ernst & Young LLP as the Company's independent auditors requires the affirmative vote of a majority of the shares represented in person or by proxy at the meeting. Proxies that abstain from voting on this proposal have the same effect as a vote against this proposal. Broker non-votes will not have any effect on this proposal.

Any shareholder executing a proxy retains the right to revoke it by signing and delivering a proxy bearing a later date, by giving notice of revocation in writing to the Secretary of the Company at any time prior to its use, or by voting in person at the meeting. All properly executed proxies received by the Company and not revoked will be voted at the meeting, or any adjournment thereof, in accordance with the specifications of the shareholder. IF NO INSTRUCTIONS ARE SPECIFIED ON THE PROXY, SHARES REPRESENTED THEREBY WILL BE VOTED FOR THE ELECTION OF THE FOUR DIRECTOR NOMINEES DESCRIBED HEREIN, FOR THE APPROVAL OF THE AMENDED AND RESTATED 1996 DIRECTOR STOCK PLAN AND FOR THE RATIFICATION OF ERNST & YOUNG LLP AS THE COMPANY'S INDEPENDENT AUDITORS FOR THE FISCAL YEAR ENDING JANUARY 31, 2003. PROXIES ALSO GRANT DISCRETIONARY AUTHORITY AS TO MATTERS PRESENTED AT THE MEETING OF WHICH THE BOARD OF DIRECTORS HAD NO NOTICE ON THE DATE HEREOF, APPROVAL OF THE MINUTES OF THE PRIOR ANNUAL MEETING AND MATTERS INCIDENT TO THE CONDUCT OF THE MEETING.

3

# VOTING SECURITIES AND OWNERSHIP THEREOF BY CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

At the close of business on April 24, 2002, the record date for the 2002 Annual Meeting of Shareholders, the Company had outstanding 28,465,677 shares of Common Stock, without par value. Each outstanding share of Common Stock is entitled to one vote with respect to each of the four director positions, one vote with respect to the approval of the Amended and Restated 1996 Director Stock Plan and one vote with respect to the ratification of Ernst & Young LLP as the Company's independent auditors for the fiscal year ending January 31, 2003. Cumulative voting is not permitted under the Company's Third Restated Articles of Incorporation. Shareholders of record at the close of business on April 24, 2002 are entitled to vote at, or execute proxies relating to, the 2002 Annual Meeting of Shareholders.

The following table lists the beneficial ownership of shares of the Company's Common Stock by (i) all persons and groups known by the Company to own beneficially more than 5% of the outstanding shares of the Company's Common Stock, (ii) each director and nominee, (iii) each person who held the office of

Chief Executive Officer during the last fiscal year and the four additional highest compensated executive officers who were serving as executive officers on January 31, 2002, and (iv) all directors and officers as a group. None of the directors, nominees or officers of the Company owned any equity security issued by the Company's subsidiaries other than director's qualifying shares. Information with respect to officers, directors and their families is as of February 28, 2002 and is based on the books and records of the Company and information obtained from each individual. Information with respect to institutional shareholders is based upon the Schedule 13D or Schedule 13G filed by such shareholders with the Securities and Exchange Commission. Unless otherwise stated, the business address of each individual or group is the same as the address of the Company's principal executive office.

AMOUNT	AND	NATURE	OF
BENEFIC	CIAL	OWNERSH	HIP

NAME OF INDIVIDUAL OR GROUP	SOLE VOTING POWER	VOTING	SOLE INVESTMENT POWER	INVESTMEN		
5% OR GREATER SHAREHOLDERS						
Barclays Global Fund Advisors 45 Fremont Street						
San Francisco, CA 94105	1,846,566	-0-	1,900,936	-0-		
J. L. Kaplan Associates, L.L.C	1,423,900	-0-	1,851,785	-0-		
Stevenson Voting Group (1) c/o Donald E. Stevenson P.O. Box 1637 Houston, TX 77251	1,699,679	1,976	1,699,679	1,976		
FMR Corp82 Devonshire Street						
Boston, MA 02109	210,400	-0-	1,517,230	-0-		

4

DIRECTORS AND NOMINEES				
Donald E. Stevenson	473,596	1,976	473,596	1,976
Robert S. Sullivan	3 <b>,</b> 376	-0-	3 <b>,</b> 376	-0-
Khleber V. Attwell	5 <b>,</b> 850	-0-	5,850	-0-
Darvin M. Winick	3,287	-0-	3,287	-0-
Howard Wolf	7,287	-0-	7,287	-0-
Michael L. Grimes	21,390	-0-	21,390	-0-
Monroe M. Luther	6,266	-0-	6,266	-0-
Charles R. Ofner	1,266	-0-	1,266	-0-

Max L. Lukens	4,342 13,890	-0- 7 <b>,</b> 250	4,342 19,190	-0- 1,950
NON-DIRECTOR EXECUTIVE OFFICERS				
John H. Doster	12,000	-0-	12,000	-0-
Richard M. Wiater	5,000	-0-	5,000	-0-
Carl B. King	-0-	-0-	-0-	-0-
Wade F. Sperry	-0-	-0-	-0-	-0-
ALL DIRECTORS AND EXECUTIVE OFFICERS				
(23 Persons)	564,240	16,476	572 <b>,</b> 840	5 <b>,</b> 876

## \* Less than 1%

- According to an amended Schedule 13D filed with the Securities and Exchange Commission, Donald E. Stevenson, Keith T. Stevenson, the Donald E. Stevenson Testamentary Trust (of which Donald E. Stevenson is trustee) and the Estate of Madlin Stevenson (of which Donald E. Stevenson and Keith T. Stevenson are co-executors) are parties to a voting agreement. The voting agreement provides that the parties thereto will agree how to vote all of the shares of Common Stock currently owned by those parties (and any after acquired shares of Common Stock if the addition is approved by the holders of a majority of the shares subject to the voting agreement at that time) on any matter submitted by the Company to a shareholder vote. If the parties to the voting agreement fail to unanimously agree how to vote such shares, such parties agree to vote in accordance with the wishes of Donald E. Stevenson. The voting agreement will terminate on January 31, 2010 unless earlier terminated by a majority vote of the shares subject to the voting agreement. The shares of Common Stock described as beneficially owned by Donald E. Stevenson are included in the Stevenson Voting Group.
- (2) Includes options to purchase 72,200 shares of Common Stock.
- (3) Includes options to purchase 29,100 shares of Common Stock.
- (4) Includes options to purchase 10,000 shares of Common Stock.
- (5) Includes options to purchase 7,000 shares of Common Stock.
- (6) Includes options to purchase 6,000 shares of Common Stock.
- (7) Includes options to purchase 77,250 shares of Common Stock.
- (8) Includes options to purchase 3,000 shares of Common Stock.
- (9) Includes options to purchase 38,225 shares of Common Stock.
- (10) Includes options to purchase 30,000 shares of Common Stock.
- (11) Includes options to purchase 3,500 shares of Common Stock.(12) Includes options to purchase 5,000 shares of Common Stock.
- (13) Includes options to purchase 249,275 shares of Common Stock.

5

## ELECTION OF DIRECTORS

The Board of Directors of the Company consists of ten directors divided into two classes of three members and one class of four members. At each Annual Meeting of Shareholders one class is elected to hold office for a term of three years. Members of the other classes continue to serve for the remainder of their respective terms. In accordance with the Bylaws of the Company, a director must

retire as of the date of the Annual Meeting of Shareholders first occurring following such director's 73rd birthday. The persons named below have been nominated for election to the Board of Directors at the Annual Meeting to serve as directors until 2005.

Each of the nominees currently serves as a director of the Company and has consented to be named herein and to serve if elected. The Board of Directors believes that each of the nominees will be willing and able to serve. If any such person is unable to serve for good cause, or is unwilling to serve for any reason, proxies will be voted for the election of another person selected by the Corporate Governance Committee of the Board of Directors. THE BOARD OF DIRECTORS RECOMMENDS THAT THE SHAREHOLDERS ELECT THE NOMINEES LISTED BELOW. UNLESS OTHERWISE SPECIFIED, ALL PROPERLY EXECUTED PROXIES RECEIVED BY THE COMPANY WILL BE VOTED AT THE ANNUAL MEETING OR ANY ADJOURNMENT THEREOF FOR THE ELECTION OF THE FOUR PERSONS WHOSE NAMES ARE LISTED IN THE FOLLOWING TABLE AS NOMINEES FOR DIRECTORS WHOSE TERM WILL EXPIRE IN 2005. PROXIES CANNOT BE VOTED FOR A GREATER NUMBER OF PERSONS THAN THE NUMBER OF NOMINEES NAMED BELOW.

PERSONS NOMINATED FOR DIRECTOR WHOSE TERM WILL EXPIRE IN 2005

NAME AND PRINCIPAL OCCUPATION	AGE
KHLEBER V. ATTWELL (1)(3)(4)	71
Management consulting (private practice). Previously, partner with Ernst $\&$ Young LLP	
C. JIM STEWART III	53
Vice President of the Company	
DARVIN M. WINICK, PH.D. (1)(3)(4)	72
President of Winick Consultants, Organizational Consultants Director for Maxim Bank. Senior Research Fellow at The University of Texas at Austin	
HOWARD WOLF (2)(4)	67
Senior Partner of the international law firm of Fulbright & Jaworski LLP. Serves as a director of Offshore Logistics, Inc. of Lafayette, Louisiana	

6

THE FOLLOWING PERSONS HAVE BEEN PREVIOUSLY ELECTED AS DIRECTORS OF THE COMPANY AND WILL CONTINUE TO SERVE AFTER THE ANNUAL MEETING.

DIRECTORS WHOSE TERM EXPIRES IN 2003

NAME AND PRINCIPAL OCCUPATION	AGE
MICHAEL L. GRIMES (1)  President and Chief Executive Officer of the Company	52
Previously, President of Cooper Cameron Power Generation, President of Cooper Energy Services, and General Manager of various operations within the General Electric Company	
MONROE M. LUTHER (2)(3)	61
Chairman of Wind River Capital Company, Chairman of The Prague Post, and Chairman of Bigger Than That Productions. Founder and former Chief Executive Officer of Eagle Management & Trust Company. Member of Advisory Board of MCG Dulworth	
CHARLES R. OFNER (2)(4)	56
Private Investor. Previously, Senior Vice President of R&B Falcon Corporation until its merger with Transocean Sedco Forex, Inc. on January 31, 2001. Previously, Senior Vice President of Reading & Bates Corporation	
DIRECTORS WHOSE TERM EXPIRES IN 2004	
NAME AND PRINCIPAL OCCUPATION	
DONALD E. STEVENSON (1)	• • •
Vice President of the Company	
ROBERT S. SULLIVAN (1)	• • •
Chairman of the Board of the Company. Dean, Kenan-Flagler Business School of the University of North Carolina at Chapel Hill. Previously, Director of the IC2 Institute, The University of Texas at Austin, Austin, Texas, and Dean of the Graduate School of Industrial Administration, Carnegie Mellon University, Pittsburgh, Pennsylvania	
MAX L. LUKENS (2)(3)	
Business consultant and investor. Previously, Chairman of the Board, President and Chief Executive Officer of Baker Hughes Incorporated	
7	

8

- (1) Member of Executive Committee.
- (2) Member of Compensation and Management Development Committee.
- (3) Member of Audit Committee.
- (4) Member of Corporate Governance Committee.

Each nominee and current director has been employed for more than five years either as shown in the foregoing table or in various executive capacities with the Company. Mr. Khleber V. Attwell, Mr. Darvin M. Winick and Mr. Howard Wolf were last elected as directors at the 1999 Annual Meeting.

#### MEETINGS AND COMMITTEES OF THE BOARD OF DIRECTORS

The Board of Directors held seven meetings during the fiscal year ended January 31, 2002 ("Fiscal 2001"). During Fiscal 2001, no director attended fewer than 75% of the aggregate of (a) the total number of meetings of the Board of Directors (held during the period for which he was a director) and (b) the total number of meetings held by all committees of the Board of Directors on which he served (during the periods that he served).

The Audit Committee of the Board of Directors consists of four independent (as defined in Rule 4200(a)(15) of the National Association of Securities Dealers' listing standards) non-employee directors. The Audit Committee reviews with the Company's independent auditors the plan, scope and results of the annual audit; reviews with the Company's independent auditors and internal auditors the procedures for and results of internal auditing and controls; and reviews with management the effectiveness of various operational policies and controls. The Audit Committee recommends to the Board of Directors the employment of independent auditors and considers, in general, the audit services to be performed by such independent auditors and the possible effect on the independence of the independent auditors from the performance of non-audit services. The Board of Directors has adopted a written charter governing the responsibilities of the Audit Committee, a copy of which is attached as Exhibit A to these proxy materials. The Audit Committee held thirteen meetings during Fiscal 2001.

The Compensation and Management Development Committee recommends the total compensation payable by the Company to its executive officers, subject to approval by those members of the Board of Directors that are not and never have been an officer of the Company or its subsidiaries; grants options pursuant to the option plans relating to officers and employees; conducts such investigations and studies as it deems necessary; and considers management succession and related matters. The Compensation and Management Development Committee held three meetings during Fiscal 2001.

The Corporate Governance Committee selects nominees for the Board of Directors of the Company. The Corporate Governance Committee considers nominees submitted by

8

the members of the Board of Directors, the officers of the Company and the Company's shareholders. Nominees for the Board of Directors may be submitted to the Chairman of the Corporate Governance Committee at the Company's executive offices for consideration by the Corporate Governance Committee. In addition, the Corporate Governance Committee administers the principles and practices established by the Board of Directors. The Corporate Governance Committee held three meetings during Fiscal 2001.

COMPENSATION COMMITTEE INTERLOCKS AND INSIDER PARTICIPATION

The Company's Compensation and Management Development Committee (the "Compensation Committee") consists of Messrs. Charles R. Ofner, Max L. Lukens, Monroe M. Luther and Howard Wolf, all of whom are non-employee directors. None of the Compensation Committee members has served as an officer of the Company, and none of the Company's executive officers has served as a member of a compensation committee or board of directors any other entity that has an executive officer serving as a member of the Company's Board of Directors.

#### COMPENSATION OF DIRECTORS

During Fiscal 2001, directors whose principal occupation is other than employment with the Company were compensated at the rate of \$15,000 per year plus \$1,000 for each meeting of the Board of Directors and each committee meeting attended in person and \$500 for each meeting attended by telephone. Each committee chairman received an annual fee of \$4,000. The Chairman of the Board received additional compensation in the amount of \$18,000. The directors were also reimbursed for any out-of-pocket expenses incurred to attend meetings. The Company has a retirement plan for directors, but accrual of benefits thereunder terminated after the 1997 Annual Meeting. Under such retirement plan, non-employee directors, including those directors that are retired officers of the Company, with 60 months of continuous service on the Board of Directors will receive \$1,000 per month for a period equivalent to service on the Board of Directors up to a maximum of 120 months, commencing on the month following their 70th birthday or the date such director ceases to serve on the Board, whichever is later.

During Fiscal 2001, each director who was not an officer or employee of the Company participated in the 1996 Director Stock Plan (the "1996 Plan"). Under the 1996 Plan, such directors received, on the date of the Annual Meeting in 2001, (i) the number of shares of the Company's Common Stock determined by dividing (A) the sum of \$15,000 by (B) the fair market value of a share of the Company's Common Stock, and (ii) options to purchase 3,000 shares of the Company's Common Stock. The options were granted at the closing price on the date of grant and will become exercisable on the first anniversary of the grant. All options granted under the 1996 Plan expire on the tenth anniversary of the grant.

9

## AMENDED AND RESTATED 1996 DIRECTOR STOCK PLAN

On April 9, 2002, the Board of Directors adopted the Stewart & Stevenson Services, Inc. Amended and Restated 1996 Director Stock Plan (the "Amended and Restated 1996 Plan"), subject to the approval thereof by the shareholders of the Company. The Amended and Restated 1996 Plan was adopted primarily (i) because most of the shares available for grant under the existing 1996 Director Stock Plan had been granted, and (ii) to maintain market-rate benefits for our non-employee directors and allow us to continue to attract high-quality independent non-employee directors. The Amended and Restated 1996 Plan is intended to encourage the ownership of the Company's Common Stock by the independent directors of the Company and to provide an additional means for the Company to attract and retain qualified persons to act as independent directors of the Company. THE BOARD OF DIRECTORS RECOMMENDS THAT THE SHAREHOLDERS APPROVE THE AMENDED AND RESTATED 1996 PLAN. UNLESS OTHERWISE INDICATED, ALL PROPERLY EXECUTED PROXIES RECEIVED BY THE COMPANY WILL BE VOTED FOR SUCH APPROVAL AT THE ANNUAL MEETING OR ANY ADJOURNMENT THEREOF. The summary of the Amended and

Restated 1996 Plan set forth below is qualified in its entirety by reference to the Amended and Restated 1996 Plan, a copy of which is included as Exhibit B to these proxy materials.

ELIGIBILITY; DIRECTOR STOCK AWARDS; GRANT OF OPTIONS

Each director that is not an officer or employee of the Company or one of its subsidiaries on the date of grant is eligible to participate in the Amended and Restated 1996 Plan. On the date hereof, there are seven directors eligible to participate in the Amended and Restated 1996 Plan.

On the date of each Annual Meeting of Shareholders, the Amended and Restated 1996 Plan provides for the automatic award and issue to each eligible director who is elected to serve as a director at, or whose term as director continues after, such meeting, the number of shares of the Company's Common Stock determined by dividing (i) the sum of \$15,000 by (ii) the fair market value of a share of the Company's Common Stock on the date of such meeting.

Also on the date of each Annual Meeting of Shareholders, the Amended and Restated 1996 Plan provides for the automatic grant of an option to purchase 5,000 shares of the Company's Common Stock to each eligible director who is elected to serve as a director at, or whose term as director continues after, such meeting. The Board of Directors may, in its discretion by majority vote, increase or decrease the number of shares subject to such automatic grant. Additionally, the Amended and Restated 1996 Plan provides that the Board of Directors may, from time to time in their discretion, grant one or more eligible director(s) an additional option to purchase shares of the Company's Common Stock.

#### DESCRIPTION OF OPTIONS

Options granted pursuant to the Amended and Restated 1996 Plan have an exercise price equal to the last transaction price reported by the National Association of Securities Dealers Automated Quotation, National Market System on the date of grant, or if there is no transaction on the date of grant, on the first preceding date on which there is a transaction in the Company's Common Stock. The Company will not (i) decrease the exercise price of any option

10

after the date of grant or (ii) permit outstanding options to be surrendered to the Company as consideration for the grant of new options with a lower exercise price.

Such options vest and become exercisable on the first anniversary of the grant and become fully vested and immediately exercisable if the recipient dies, fails to stand for re-election or be re-elected, or retires after serving at least 60 consecutive calendar months as a director of the Company. Options also become fully vested and immediately exercisable if the Company merges, consolidates or combines with another company and the Company is not the surviving entity. All options granted pursuant to the Amended and Restated 1996 Plan terminate on the tenth anniversary of the date of grant or one year after recipient ceases to be a director of the Company, whichever first occurs. The exercise price under any option may be paid either in cash or by delivering certificates representing shares of the Company's Common Stock having a market value on the date of exercise equal to the exercise price.

FEDERAL INCOME TAX CONSEQUENCES

The options are not intended to qualify for any special tax treatment under any provision of the Internal Revenue Code of 1986, as amended. The grant of options under the Amended and Restated 1996 Plan will not result in taxable income to the recipient or a deduction to the Company on the date of grant. The recipient will be deemed to have received taxable income, and the Company will be entitled to a deduction equal to the difference between the market price and the exercise price at the time an option is exercised.

#### AMENDMENTS

The Board of Directors may amend, suspend or terminate the Amended and Restated 1996 Plan at any time. However, no such amendment, suspension or termination will affect any outstanding stock award or option without the holder's consent.

The following table sets forth the estimated annual benefits that will be received by each of the persons or groups set forth therein under the Amended and Restated 1996 Plan if approved by the shareholders.

# NEW PLAN BENEFITS AMENDED AND RESTATED 1996 DIRECTOR STOCK PLAN

	DOLLAR	NUMBER OF
NAME AND POSITION	VALUE (\$)	OPTIONS
Non-Executive Director Group	\$105 <b>,</b> 000	35,000

11

#### SELECTION OF INDEPENDENT AUDITORS

The Board of Directors, upon recommendation of the Audit Committee, has appointed Ernst & Young LLP as independent auditors of the Company for the fiscal year ending January 31, 2003. Arthur Andersen LLP served as the Company's independent auditors for the fiscal year ended January 31, 2002. THE BOARD OF DIRECTORS RECOMMENDS THAT THE APPOINTMENT OF ERNST & YOUNG LLP AS INDEPENDENT AUDITORS FOR THE COMPANY FOR THE FISCAL YEAR ENDING JANUARY 31, 2003 BE RATIFIED BY THE SHAREHOLDERS. UNLESS OTHERWISE INDICATED, ALL PROPERLY EXECUTED PROXIES RECEIVED BY THE COMPANY WILL BE VOTED FOR SUCH RATIFICATION AT THE ANNUAL MEETING OR ANY ADJOURNMENT THEREOF. An adverse vote will be considered a direction to the Audit Committee to select other independent auditors in the following year.

On April 22, 2002, the Board of Directors, upon recommendation of the Audit Committee, made a determination to no longer engage Arthur Andersen LLP ("Arthur Andersen") as its independent auditors and appointed Ernst & Young LLP as the Company's independent auditors for the fiscal year ending January 31, 2003.

Arthur Andersen's reports on the Company's consolidated financial statements for the fiscal years ended January 31, 2002 and 2001 did not contain an adverse opinion or disclaimer of opinion, nor were they qualified or modified as to uncertainty, audit scope or accounting principles.

During the fiscal years ended January 31, 2002 and 2001 and through the date of the dismissal of Arthur Andersen, there were no disagreements with Arthur Andersen on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure which, if not resolved to Arthur Andersen's satisfaction, would have caused it to make reference to the subject matter in connection with its report on the Company's consolidated financial statements for such years; and there were no reportable events as specified in Item 304(a)(1)(v) of Regulation S-K.

During the fiscal years ended January 31, 2002 and 2001 and through the date of the dismissal of Arthur Andersen, the Company did not consult Ernst & Young LLP with respect to the application of accounting principles to a specified transaction, either completed or proposed, or the type of audit opinion that might be rendered on the Company's consolidated financial statements, or any other matters or reportable events as set forth in Items 304(a)(2)(i) and (ii) of Regulation S-K. A representative of Ernst & Young LLP will be present at the Annual Meeting to make a statement if such representative desires and to respond to appropriate questions. A representative of Arthur Andersen LLP has been invited to attend the Annual Meeting to make a statement if such representative desires and to respond to appropriate questions.

#### AUDIT FEES

The aggregate fees billed for professional services rendered by Arthur Andersen for the audit of the Company's financial statements for the fiscal year ended January 31, 2002 and for the reviews of the financial statements included in the Company's Quarterly Reports on Form 10-Q for that fiscal year were approximately \$745,000.

12

#### FINANCIAL INFORMATION SYSTEMS DESIGN AND IMPLEMENTATION FEES

Arthur Andersen did not perform any financial information system design or implementation work for the Company during the fiscal year ended January 31, 2002.

### ALL OTHER FEES

The aggregate fees billed for all other professional services rendered by Arthur Andersen for the fiscal year ended January 31, 2002 were approximately \$1,232,000. The Audit Committee considered whether, and has determined that, the provision of these services was compatible with maintaining Arthur Andersen's independence.

NOTWITHSTANDING ANY STATEMENT CONTAINED IN A PREVIOUS FILING BY THE COMPANY UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED, NEITHER THE PERFORMANCE GRAPH SET FORTH BELOW NOR THE REPORT OF THE COMPENSATION AND MANAGEMENT DEVELOPMENT COMMITTEE OR THE REPORT OF THE AUDIT COMMITTEE THAT FOLLOWS IS INCORPORATED BY REFERENCE INTO ANY SUCH FILING.

#### PERFORMANCE OF STEWART & STEVENSON COMMON STOCK

The following graph compares the cumulative total shareholder return on the Company's Common Stock to the cumulative total shareholder return of the S&P 500 Industrial Machinery Index and the S&P Smallcap 600 Index for the Company's last five fiscal years. The graph assumes that the value of an investment in the

Company's Common Stock and each index was \$100 on January 31, 1997 and that all dividends were reinvested.

[PERFORMANCE GRAPH]

#### YEAR ENDED JANUARY 31,

	1997	1998 	1999	2000	2001	2002
Stewart & Stevenson Services, Inc.	100	99	35	47	110	78
S&P Smallcap 600 Index	100	121	120	133	160	165
S&P 500 Industrial Machinery Index	100	129	126	128	145	154

13

REPORT OF THE COMPENSATION AND MANAGEMENT DEVELOPMENT COMMITTEE

TO THE SHAREHOLDERS OF STEWART & STEVENSON SERVICES, INC.

The Compensation and Management Development Committee of the Board of Directors (the "Committee") consists of four independent, non-employee directors who have no "interlocking" relationships as defined by the Securities and Exchange Commission. The Committee reviews and recommends all salary arrangements and other executive compensation for approval by the independent members of the Board of Directors, approves the design of executive compensation programs, administers such programs and assesses their effectiveness in supporting the Company's compensation policies. The Committee also evaluates executive performance and considers management succession and related matters. The Committee is authorized to, and does, retain independent consultants to assist in the design of compensation programs and assess their effectiveness.

The Committee is committed to implementing a compensation program that encourages creation of shareholder value. To facilitate the achievement of the Company's business strategies, the Committee adheres to the following compensation policies:

To strengthen the relationship between pay and performance, executive's annual and long-term compensation programs will include variable compensation that is dependent upon the contribution of each executive to the Company's performance.

To focus management on the achievement of both short-term performance goals and the long-term interests of shareholders, a significant portion of each executive's total compensation will consist of "at-risk" compensation.

To enable the Company to attract, retain and encourage the development of

the best available executive personnel, competitive compensation opportunities will be offered.

The Committee, with the assistance of its independent compensation consultants, has evaluated the function of each executive position to determine the skill, knowledge, and accountability required. Using this information, the Committee is able to compare the compensation of each executive officer with a broad base of compensation paid to others occupying positions with a similar relative job content.

#### TOTAL COMPENSATION

The key elements of the Company's executive compensation program are base salary, annual incentives and long-term incentives, each of which is addressed separately below. In determining each component of compensation, the Committee considers all elements of an executive's total compensation package and the relationship of such executive's total compensation to the total compensation paid to the executives with similar position content.

Mr. Michael L. Grimes served as President and Chief Executive Officer of the Company during the twelve months ended January 31, 2002 ("Fiscal 2001"). Total compensation paid to Mr. Grimes during Fiscal 2001 was below the median amount paid to other executives with similar position content. Total compensation paid to other executive officers of the Company was

14

generally consistent with the median total compensation paid to executives with similar position content. However, relative competitiveness of compensation varied significantly among individual executives largely due to historical practice, changes in roles and responsibilities, and new hirings.

#### BASE SALARY

Base salary levels are targeted at the median levels of compensation for executives with similar position content and targeted within a range of plus or minus 20% of the median. The Committee reviews each executive's salary on an annual basis. Increases to base salaries are driven primarily by changes in the relative job content of the executive's position, the expected contributions of the executive in the upcoming fiscal year, and changes in the competitive market compensation practice. Individual performance, experience, past performance and historical salary levels are also considered. In making its evaluation, the Committee has not assigned particular weights to these factors.

Base salaries established by the Committee for Fiscal 2001 were generally within the administrative range. Several officers' salaries were above the median for positions with similar job content because of recent assignment to new positions or decreases in content during prior periods. Mr. Grimes' base salary was below the median base salary for positions with similar content.

## ANNUAL INCENTIVES

The Company provides an annual bonus opportunity to executives. Annual bonuses motivate executives to maximize short-term performance as a part of achieving long-term goals.

At the beginning of Fiscal 2001, the Committee and the Company adopted a Management Incentive Compensation Plan ("MICP") providing for cash bonus opportunities for individual executive officers between 10% and 60% of their

base salary if certain individual and Company performance targets are met. In determining the relative percentage of base salary for each individual executive's bonus opportunity, the Committee considered the aggregate total compensation paid by the Company to such person compared to amounts paid by other companies to executives with similar position content. The performance targets used in the MICP to determine whether all or part of an individual executive's bonus opportunity is awarded, are based upon (i) the performance of the Company compared to pre-established goals, (ii) the performance of a particular cost center, profit center, or business function for which each individual executive is responsible compared to pre-established goals, and (iii) the commitment of the individual to ethical business practices. Approximately 70% of the target bonus for each executive officer is based on financial measurements of the Company's and/or individual profit center performance and the balance is based on non-financial goals and considerations.

Bonus payments approved by the Committee for Fiscal 2001 were calculated under the terms of the MICP. In determining the criteria for Mr. Grimes' bonus opportunity under the MICP, the Committee considered Mr. Grimes' measured accomplishments as CEO, as well as the total compensation packages of senior executives with similar responsibilities.

15

#### LONG-TERM INCENTIVES

In keeping with the Company's philosophy of providing a total compensation package favoring "at-risk" components of pay, long-term incentives comprise a significant portion of each executive's total compensation package. Long-term incentives during Fiscal 2001 consisted exclusively of stock options pursuant to the Stewart & Stevenson 1988 Nonstatutory Stock Option Plan. Stock options under this plan are granted at an option price not less than the fair market value of the Common Stock on the date of grant. Accordingly, stock options have a value only if the stock price appreciates from the date the options are granted. The design of these stock options focuses executives on the creation of shareholder value over the long term and encourages equity ownership in the Company.

The size of award to each executive is affected by individual performance, the individual's level of responsibility, and the desire of the Company to retain the individual. As a result, the number of shares underlying stock option awards varies from year to year and is dependent on the stock price on the date of grant.

#### POLICY WITH RESPECT TO THE \$1 MILLION DEDUCTION LIMIT

Section 162(m) of the Internal Revenue Code of 1986, as amended, generally limits the corporate deduction for compensation paid to executive officer named in the proxy to \$1 million per year, unless certain requirements are met. The Committee has carefully considered the impact of this provision on the Company's incentive plans and has determined that Section 162(m) is currently inapplicable because no named executive officer is expected to receive compensation, other than performance-based compensation, in excess of \$1 million in the foreseeable future. The Committee believes it is in the Company's best interest to retain some non-formula evaluation of individual performance when determining total compensation payable to the Company's executive officers.

## CONCLUSION

The Committee believes these executive compensation policies and programs serve the interests of the shareholders and the Company effectively. The various pay vehicles offered are appropriately balanced to provide increased motivation for

executives to contribute to the Company's overall future success, thereby enhancing the value of the Company for the shareholders' benefit. The Committee will continue to monitor the effectiveness of the Company's total compensation program to meet the current needs of the Company.

Respectfully submitted,
THE COMPENSATION AND MANAGEMENT DEVELOPMENT
COMMITTEE

Charles R. Ofner - Chairman Max L. Lukens Howard Wolf Monroe M. Luther

THE INFORMATION IN THE FOREGOING PARAGRAPHS SHALL NOT BE DEEMED TO BE SOLICITING MATERIAL, OR BE FILED WITH THE SECURITIES AND EXCHANGE COMMISSION OR SUBJECT TO REGULATION 14A OR 14C OR TO LIABILITIES OF SECTION 18 OF THE SECURITIES EXCHANGE ACT OF 1934, NOR SHALL IT BE DEEMED TO BE INCORPORATED BY REFERENCE INTO ANY FILING UNDER THE SECURITIES ACT OF 1933 OR SECURITIES EXCHANGE ACT OF 1934, EXCEPT TO THE EXTENT THE COMPANY SPECIFICALLY INCORPORATES THESE PARAGRAPHS BY REFERENCE.

16

#### REPORT OF THE AUDIT COMMITTEE

TO THE SHAREHOLDERS OF STEWART & STEVENSON SERVICES, INC.

The Audit Committee of the Board of Directors (the "Audit Committee") has:

- Reviewed and discussed the audited financial statements for the fiscal year ended January 31, 2002 with the management of the Company;
- 2. Discussed with the Company's Independent Auditors the matters required to be discussed by Statement of Accounting Standards No. 61, as the same was in effect on the date of the Company's financial statements; and
- 3. Received the written disclosures and the letter from the Company's Independent Auditors required by Independence Standards Board Standard No. 1 (INDEPENDENCE STANDARDS BOARD STANDARD NO. 1, INDEPENDENCE DISCUSSIONS WITH AUDIT COMMITTEES), as the same was in effect on the date of the Company's financial statements, and has discussed with the Independent Auditors their independence.
- 4. Received representations from Arthur Andersen LLP ("Andersen") that the audit of the Company's financial statements was subject to Andersen's quality control system for the U.S. accounting and auditing practice to provide reasonable assurance that the engagement was conducted in compliance with professional standards and that there was appropriate continuity of Andersen personnel working on audits, availability of national office consultation, and availability of personnel at foreign affiliates of Andersen to conduct the relevant portions of the audit.

Based on the foregoing materials and discussions, the Audit Committee recommended to the Board of Directors that the audited financial statements for the fiscal year ended January 31, 2002 be included in the Company's Annual Report on Form 10-K.

Respectfully submitted, THE AUDIT COMMITTEE

Khleber V. Attwell - Chairman
Darvin M. Winick
Monroe M. Luther
Max L. Lukens

THE INFORMATION IN THE FOREGOING PARAGRAPHS SHALL NOT BE DEEMED TO BE SOLICITING MATERIAL, OR BE FILED WITH THE SECURITIES AND EXCHANGE COMMISSION OR SUBJECT TO REGULATION 14A OR 14C OR TO LIABILITIES OF SECTION 18 OF THE SECURITIES EXCHANGE ACT OF 1934, NOR SHALL IT BE DEEMED TO BE INCORPORATED BY REFERENCE INTO ANY FILING UNDER THE SECURITIES ACT OF 1933 OR SECURITIES EXCHANGE ACT OF 1934, EXCEPT TO THE EXTENT THE COMPANY SPECIFICALLY INCORPORATES THESE PARAGRAPHS BY REFERENCE.

17

#### EXECUTIVE OFFICERS

The names, ages and positions of all the executive officers of the Company as of January 31, 2002 are listed below. Except as noted below, each officer was last elected as an executive officer at the meeting of directors immediately following the 2001 Annual Meeting of Shareholders. The term of each executive officer will expire at the meeting of directors following the 2002 Annual Meeting of Shareholders. There exist no arrangements or understandings between any officer and any other person pursuant to which the officer was elected.

NAME	AGE	POSITION
Michael L. Grimes	52	President and Chief Executive Officer
John H. Doster (1)	60	Senior Vice President and Chief Financial Officer
Carl B. King	59	Senior Vice President, Secretary and General Counsel
Richard M. Wiater	66	Senior Vice President
Wade F. Sperry	54	Senior Vice President
T. Michael Andrews	61	Vice President
Donald E. Stevenson	58	Vice President
C. Jim Stewart III	53	Vice President
Ralston P. Cole	64	Vice President
David R. Stewart	51	Treasurer
Ralph T. Tierno III	46	Vice President
Stephen A. Hines	53	Vice President
James C. Farris	49	Vice President
John E. Keating (2)	62	Vice President
Peter J. DeFronzo	59	Vice President
Caldwell Phillip Joy	43	Vice President
John B. Simmons	49	Controller and Chief Accounting Officer

<sup>(1)</sup> Mr. John H. Doster announced his intention to resign from the offices of Senior Vice President and Chief Financial Officer effective in May, 2002.

(2) Mr. John E. Keating resigned from the office of Vice President in April, 2002.

Except as follows, each of the officers listed above has been employed by the Company in an executive capacity for more than five years.

Mr. Grimes was elected as President and Chief Executive Officer of the Company in April 1999. He previously served as President of Cooper Cameron Power Generation from 1998 to 1999, President of Cooper Energy Services from 1996 to 1998, and General Manager of various operations within the General Electric Company from 1973 to 1996.

Mr. Doster was elected as Chief Financial Officer of the Company in July 1998. He previously served as Senior Vice President and Chief Financial Officer of Battelle Memorial Institute from 1992 to 1997.

Mr. King was elected as Senior Vice President, Secretary and General Counsel of the Company in 2001. He previously served as Senior Vice President and General Counsel of Seagull Energy Corporation from 1998 to 1999, and Senior Vice President and General Counsel of PanEnergy Corporation from 1990 to 1997.

Mr. Wiater is Senior Vice President of the Company and has served in that capacity since June 1999. He previously was a personal investor and advisor to several small businesses from 1995 to 1998 after retiring from the General Electric Company.

18

Mr. Sperry was elected as Senior Vice President of the Company in 2001. He previously served as Vice President, Fossil Operations, of Florida Power Corporation from 1997 to 2000, and Region Manager of Apparatus Service for the General Electric Company.

Mr. Cole was elected as a Vice President of the Company in 1998. He previously served as the Gulf Coast Regional Manager of the Company's Power Products Division from 1995 to 1998.

Mr. David Stewart was elected as Treasurer of the Company in 1998. He previously served the Company as Director of Investor Relations and continues to serve in that position.

Mr. Tierno was elected as a Vice President of the Company in 1999. He previously served as President of Clarostat Sensors & Controls Inc., a division of Invensys PLC, from March 1998 to September 1999. He previously served as Vice President - General Manager of various divisions of Schlumberger, Ltd.

Mr. Hines was elected as a Vice President of the Company in 2000. He previously served the Company as Corporate Human Resources Manager.

Mr. Farris was elected as a Vice President of the Company in 2000. He previously served as the Company's Dallas Division Manager in the Power Products Division.

Mr. Keating was elected as a Vice President of the Company in 2000. He previously served as President of Worldwide Sales of Tug Manufacturing Corporation for more than the last five years.

Mr. DeFronzo was elected as a Vice President of the Company in 2001. He previously served as General Manager of Supply Chain Management for Cooper Energy Services from 1998 to 2001 and Product General Manager of the

Distribution Transformer Businesses for the General Electric Company from 1992 to 1997.

Mr. Joy was elected as a Vice President of the Company in 2002. He previously served as President of Trilectron Industries for more than the last five years.

Mr. Simmons was elected as Controller and Chief Accounting Officer of the Company in 2001. He previously served as Vice President and Chief Financial Officer of Cooper Energy Services from 1997 to 2000, and Chief Financial Officer of Production Operators, Inc. from 1996 to 1997.

C. Jim Stewart III and David R. Stewart are brothers, and T. Michael Andrews is a first cousin of Mr. Donald E. Stevenson. These persons and other members of the Stewart family and the Stevenson family could be deemed "control persons" with respect to the Company as such term is defined in the rules and regulations of the Securities and Exchange Commission.

19

#### EXECUTIVE COMPENSATION

The following Summary Compensation Table shows the aggregate compensation paid or accrued by the Company during each of the last three fiscal years to or for (i) any individual that held the office of Chief Executive Officer during Fiscal 2001 and (ii) each of the other four highest compensated executive officers.

#### SUMMARY OF COMPENSATION

		AN:	ANNUAL COMPENSATION				
NAME AND PRINCIPAL POSITION	FISCAL YEAR (1)	SALARY	BONUS	OTHER ANNUAL COMPEN- SATION	OPTIONS GRANTED		
Michael L. Grimes	2001	\$ 387,308	\$ 198 <b>,</b> 000	(3)	70,000		
President and Chief	2000	319,231	207,237	(3)	125,000		
Executive Officer	1999	236,015	250,000 (2)	(3)	100,000		
John H. Doster	2001	310,577	87,000	(3)	20,000		
Senior Vice President and	2000	274,423	134,000	(3)	40,000		
Chief Financial Officer	1999	260,000	125,000	(3)	40,000		
Richard M. Wiater	2001	265,000	274 <b>,</b> 900	(3)	20,000		
Senior Vice President	2000	234,615	171,080	(3)	30,000		
	1999	108,173	125,000	(3)	-0-		
Carl B. King	2001	266,539	118,500	(3)	20,000		
Senior Vice President,	2000	N/A	N/A	(3)	N/A		
Secretary and General Counsel	1999	N/A	N/A	(3)	N/A		

Wade F. Sperry	2001	250,000	94,282	(3)	-0-
Senior Vice President	2000	N/A	N/A	(3)	20,000
	1999	N/A	N/A	(3)	N/A

- (1) The Company's fiscal year ends on January 31.
- (2) Mr. Grimes' bonus compensation in Fiscal 1999 consisted of (i) a signing bonus in the amount of \$100,000 paid in April 1999, and (iii) a merit bonus in the amount of \$150,000 for the fiscal year ended January 31, 2000.
- (3) The total amount of all perquisites and other personal benefits, securities or property paid or accrued by the Company is less than the lesser of (i) \$50,000 or (ii) 10% of the total of annual salary and bonus. There have been no amounts paid or accrued with respect to above-market or preferential earnings on restricted stock, options, SARs or deferred compensation or with respect to earnings on long-term incentive plans or tax reimbursements.
- (4) Unless otherwise indicated, All Other Compensation consists of the dollar value of insurance premiums for term life insurance policies for the benefit of the named executive.

20

- (5) For each of the fiscal years ended January 31, 2002, 2001 and 2000, respectively, Other Compensation for Mr. Grimes consists of term life insurance premiums of \$970, \$1,135 and \$579, and contributions by the Company to a defined contribution pension plan of \$4,011, \$3,937 and \$4,154.
- (6) For each of the fiscal years ended January 31, 2002, 2001 and 2000, respectively, Other Compensation for Mr. Doster consists of term life insurance premiums of \$787, \$976 and \$662, and contributions by the Company to a defined contribution pension plan of \$3,738, \$3,937 and \$3,285.
- (7) For each of the fiscal years ended January 31, 2002, 2001 and 2000, respectively, Other Compensation for Mr. Wiater consists of term life insurance premiums of \$449 and \$57 (Fiscal 2001 and 2000), and contributions by the Company to a defined contribution pension plan of \$3,887, \$4,200 and \$2,250.
- (8) For the fiscal year ended January 31, 2002, Other Compensation for Mr. King consists of term life insurance premiums of \$669 and contributions by the Company to a defined contribution pension plan of \$2,538.
- (9) For the fiscal year ended January 31, 2002, Other Compensation for Mr. Sperry consists of term life insurance premiums of \$680 and contributions by the Company to a defined contribution pension plan of \$1,736.

## GRANTS AND EXERCISES OF STOCK OPTIONS AND STOCK APPRECIATION RIGHTS

The Company has three stock option plans. The 1988 Nonstatutory Stock Option Plan (as amended and restated effective as of June 10, 1997) (the "1988 Plan") authorizes the grant of options to employees, including officers, to

purchase an aggregate of up to 1,500,000 shares of Common Stock and provides that limited stock appreciation rights may be granted in connection with such options. The 1993 Nonofficer Stock Option Plan (the "1993 Plan") authorizes the grant of options to employees other than officers of the Company to purchase an aggregate of up to 818,625 shares of Common Stock. Stock appreciation rights may not be granted under the 1993 Plan. The Amended and Restated 1996 Director Stock Plan amended and restated the 1996 Director Stock Plan, was adopted by the Board on April 9, 2002 and is subject to shareholder approval as provided herein (the "Amended and Restated 1996 Plan"). The Amended and Restated 1996 Plan authorizes the grant of options to directors other than officers or employees of the Company.

The recipients and terms of options granted pursuant to the 1988 Plan and the 1993 Plan are determined by the Compensation and Management Development Committee of the Board of Directors, none of whom are employees of the Company or eligible for any benefits under such plans. Prior to its amendment and restatement, the Amended and Restated 1996 Plan provided for an automatic grant of an option to purchase 3,000 shares of the Company's Common Stock on the date of each Annual Meeting of Shareholders to each eligible director who was elected to serve as a director at, or whose term as a director continued after, such meeting. Subject to shareholder approval as provided herein, the Amended and Restated 1996 Plan will provide for an automatic grant of an option to purchase 5,000 shares of the Company's Common Stock.

21

During Fiscal 2001, the Company granted options to purchase an aggregate of (i) 208,000 shares of Common Stock under the 1988 Plan, (ii) 155,000 shares of Common Stock under the 1993 Plan and (iii) 21,000 shares of Common Stock under the 1996 Plan. No limited stock appreciation rights were granted under the 1988 Plan during Fiscal 2001 or during any previous fiscal year. The following tables set forth information as to options under the Company's stock option plans granted to or exercised by the individuals described in the Summary Compensation Table during 2001 and the value of all outstanding options owned as of January 31, 2002 by the individuals named in the Summary Compensation Table.

OPTION GRANTS DURING FISCAL 2001

INDIVIDUAL GRANTS

NAME 	OPTIONS GRANTED (1)	% OF TOTAL OPTIONS GRANTED TO EMPLOYEES	EXERCISE PRICE PER SHARE (2)	EXPIRATION DATE
Michael L. Grimes	70,000	19.3	\$20.25	03/22/2011
John H. Doster	20,000	5.5	\$20.25	03/22/2011
Richard M. Wiater	20,000	5.5	\$20.25	03/22/2011
Carl B. King	20,000	5.5	\$26.61	02/08/2011
Wade F. Sperry	-0-	0.0	N/A	N/A

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- (1) All options become exercisable in four 25% cumulative annual installments commencing March 22, 2002, except those granted to Mr. King, which become exercisable in four 25% cumulative annual installments commencing February 8, 2002.
- (2) All options are exercisable at the prices shown. The prices shown are not less than the closing market price on the date of grant.
- (3) All options expire ten years after the date of grant.

#### OPTION EXERCISES DURING FISCAL 2001 AND YEAR-END VALUES

NUMBER OF UNEXERCISED OPTIONS AT JANUARY 31, 2002

NAME 	SHARES ACQUIRED ON EXERCISE	VALUE REALIZED	EXERCISABLE	UNEXERCISABLE
Michael L. Grimes	4,000	\$ 52,415	77 <b>,</b> 250	213,750
John H. Doster	-0-	N/A	30,000	70,000
Richard M. Wiater	4,000	102,510	3,500	42,500
Carl B. King	-0-	N/A	-0-	20,000
Wade F. Sperry	-0-	N/A	5,000	15,000

22

#### RETIREMENT PLANS

The Company has a defined benefit pension plan (the "Pension Plan") under which benefits are determined primarily by average final base salary and years of service. The Pension Plan covers substantially all of its full-time employees, including officers, and, subject to certain limitations described below, bases pension benefits on 1.5% of (a) the employee's highest consecutive five-year average base salary out of the last ten years or (b) \$200,000 (and thereafter subject to adjustment for increases in the cost of living), whichever is lower, times the employee's years of credited service. The Internal Revenue Code of 1986, as amended, limits benefits that may be paid under the Pension Plan to \$160,000 per year in 2002, offset by a compensation of Social Security benefits.

The Company has a Supplemental Executive Retirement Plan (the "SERP") under which certain key executives will receive retirement benefits in addition to those provided under the Pension Plan. The Compensation and Management Development Committee determines which executive officers are eligible for benefits under the SERP. Supplemental benefits are based upon the average final compensation and years of service without regard to the limitations imposed by the Internal Revenue Code of 1986, as amended, and using the total of base salary and bonus to compute final average compensation. Benefits under the SERP are limited to an amount such that the aggregate of all retirement benefits paid under the Pension Plan and the SERP will not exceed 75% of the executive's highest consecutive five-year average salary, not including bonus payments.

23

The following table sets forth the estimated annual benefits payable upon retirement to persons in specified compensation and years-of-service classification pursuant to the Stewart & Stevenson Employee Pension Plan and the Stewart & Stevenson Supplemental Executive Retirement Plan.

## ESTIMATED ANNUAL RETIREMENT BENE YEARS OF SERVICE

FINAL AVERAGE COMPENSATION	20	25 	30	35 
\$100,000	\$ 24,438	\$ 30,548	\$ 36,657	\$ 43,230
200,000	54,438	68,048	81,657	95 <b>,</b> 730
300,000	84,438	105,548	126,657	148,230
400,000	114,438	143,048	171,657	200,730
500,000	144,438	180,548	216,657	253,230
600,000	174,438	218,048	261,657	305,730
700,000	204,438	255,548	306,657	358,230
800,000	234,438	293,048	351,657	410,730
900,000	264,438	330,548	396,657	463,230
1,000,000	294,438	368,048	441,657	515,730

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The Stewart & Stevenson Pension Plan provides benefits based on compensation less than or equal to the maximum amount under Internal Revenue Code of 1986, as amended (the "IRC") Section 401(a)(17). Qualified plan benefits are limited by IRC Section 4115. Benefits that exceed these limits are provided through a non-qualified plan to eligible SERP participants.

(1) Computation of estimated annual retirement benefit based on a straight-line annuity for the life of the employee, net of base Social Security benefits under the Social Security law currently in effect, assuming the employee retires in 2001 at age 65.

The five-year average compensation of each executive officer listed in the Summary of Compensation Table differs from the present salary and bonus in such table as a result of changes in the rate of pay during the average period. The following table sets forth the years of credited service, five-year average compensation and consecutive five-year average base salary for each of the individuals listed in the Summary of Compensation Table.

NAME	YEARS OF SERVICE	AVERAGE TOTAL COMPENSATION	AVERAGE BASE SALARY
Michael L. Grimes	3	N/A	N/A
John H. Doster	4	N/A	N/A
Richard M. Wiater	3	N/A	N/A
Carl B. King	1	N/A	N/A
Wade F. Sperry	1	N/A	N/A

24

#### TRANSACTIONS WITH MANAGEMENT AND CERTAIN BUSINESS RELATIONSHIPS

Mr. Howard Wolf is a partner in the international law firm of Fulbright & Jaworski L.L.P., which provides legal services to the Company.

#### SECTION 16(A) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

Section 16(a) of the Securities Exchange Act of 1934 requires the Company's officers, directors and persons who own more than 10% of a registered class of the Company's equity securities to file reports of ownership and changes in ownership with the Securities and Exchange Commission. Officers, directors and greater than 10% stockholders are required by the regulation to furnish the Company with copies of all Section 16(a) reports they file.

Based solely upon a review of such reports received by it, or written representations from certain reporting persons that no Form 5 reports were required for those persons, the Company believes that, during fiscal 2001, all filing obligations applicable to the reporting persons were complied with except that: Mr. Charles R. Ofner did not timely file a Form 4 due in July 2001 (a Form 4 was filed in August 2001).

## FORM 10-K FOR FISCAL 2001

THE COMPANY WILL PROVIDE WITHOUT CHARGE TO ANY SHAREHOLDER ENTITLED TO VOTE AT THE ANNUAL MEETING A COPY OF ITS MOST RECENT ANNUAL REPORT ON FORM 10-K UPON RECEIPT OF A REQUEST THEREFOR. SUCH REQUESTS SHOULD BE DIRECTED TO:

CARL B. KING
SENIOR VICE PRESIDENT, SECRETARY & GENERAL COUNSEL
P.O. BOX 1637
HOUSTON, TEXAS 77251-1637
(713) 868-7700

#### SHAREHOLDER PROPOSALS FOR THE 2003 ANNUAL MEETING

Shareholders may submit proposals for the 2003 Annual Meeting by sending such proposals to the attention of the Corporate Secretary at the Company's principal executive offices, 2707 North Loop West, P.O. Box 1637, Houston, Texas 77251-1637. In order to be considered for inclusion in the proxy statement and form of proxy for the 2003 Annual Meeting, such proposals must be received by the Company on or before January 3, 2003.

By Order of the Board of Directors,

/s/ CARL B. KING Carl B. King Senior Vice President, Secretary and General Counsel

Dated: May 3, 2002 Houston, Texas

25

EXHIBIT A

STEWART & STEVENSON SERVICES, INC.

AUDIT COMMITTEE

CHARTER

#### RESPONSIBILITIES

The Audit Committee (the "Committee") of the Board of Directors (the "Board") of Stewart & Stevenson Services, Inc. (the "Company) consists of directors who are independent of the management of the Company and free to exercise independent judgment. The Committee provides assistance to the Board in fulfilling the Board's oversight of the Company's accounting and system of internal controls, the quality and integrity of the Company's financial reports and the independence and performance of the Company's independent auditor.

In the exercise of its oversight, it is not the duty of the Committee to plan or conduct audits or to determine that the Company's financial statements fairly present the Company's financial position and results of operation and are in accordance with generally accepted accounting principles. Management is responsible for the Company's internal controls, quality of financial and accounting judgments and financial reporting process. The independent auditor is responsible to perform an independent audit of the Company's consolidated financial statements in accordance with generally accepted auditing standards and to issue a report thereon. Nothing contained in this charter is intended to alter or impair the right of the members of the Committee to rely, in discharging their oversight role, on the records of the Company and on other information presented to the Committee, the Board or Company by its officers or employees or by outside experts such as the independent auditor. Nor is it the duty of the Committee to investigate or resolve disagreements, if any, between management and the independent auditors.

The Committee is responsible for receipt from the independent auditor of a formal written statement delineating all relationships between the independent auditor and the Company, consistent with Independence Standards Board Standard No. 1. The Committee shall discuss with the independent auditor with respect to any disclosed relationships or services that, in the view of the Committee, may impact the objectivity and independence of the independent auditor. If the Committee determines that further inquiry is advisable, the Committee shall recommend that the Board take any appropriate action in response to the independent auditor's independence.

On behalf of the Board, the Committee:

A. Assures that open communications exist between the directors, independent auditors, internal auditors and the financial management of the Company and recommends to the Board changes in policies, practices, or organization to improve the Company's financial management, controls or reporting.

A-1

- B. Reviews and evaluates the independent auditor and, if necessary, recommend that the Board replace the independent auditor. The Committee shall recommend to the Board the nomination of the independent auditor for stockholder approval at any meeting of stockholders. The independent auditor shall be ultimately accountable to the Committee and the Board in connection with the audit of the Company's annual financial statement and related services.
  - Prior to the annual audit, the Committee meets with the independent auditor and financial management to review the scope and cost of the audit and the procedures to be used and, at the conclusion of the audit, reviews all reports, statements, comments and recommendations of the independent auditors. The Committee shall discuss with the independent auditor the matters required to be discussed by Statement on Auditing Standards No. 61 relating to the conduct of the annual audit.
  - 2. Prior to release, the Committee reviews the financial statements to be contained in the annual report to shareholders, all reports to regulatory bodies and releases to the investment community to determine that the disclosures and content of the reports are satisfactory in the opinion of the independent auditor and legal counsel.
  - 3. Prior to the filing of the Form 10-Q, the independent auditor shall review with the Committee the interim financial statements to be included in any Form 10-Q of the Company using professional standards and procedures for conducting such reviews, as established by generally accepted auditing standards as modified or supplemented by the Securities and Exchange Commission and in accordance with Statement on Auditing Standards 71. The Committee shall discuss with management and the independent auditor the results of the quarterly review including such matters as significant adjustments, management judgments, accounting estimates, significant new accounting policies and disagreements with management.
  - 4. At least annually the Committee reviews with financial management and the independent auditors, the adequacy and effectiveness of accounting practices and internal controls of the Company, the scope and effectiveness of internal audit activities and the compliance of the Company with laws and regulatory requirements.
- C. Reviews with financial management the annual internal audit plan, determines that the independence and authority of the internal auditors are adequate and meets with the internal auditors to review their findings and recommendations.
- D. Reviews its own charter and reports the results of that review and any recommendations to the Board.

E. Prepares and approves an Audit Committee Report to be included in the Company's proxy statement as required by Item 306 of Regulations S-K of the Securities and Exchange Commission.

A-2

#### ORGANIZATION

- A. The Committee shall consist of not less than three directors who are qualified and independent. Members of the Committee shall be financially literate or become financially literate within a reasonable period of time after appointment to the Committee. At least one member of the Committee must have accounting or related financial management expertise. Committee members are independent if they meet the independence requirements of The Nasdaq Stock Market, Inc.
- B. At least four meetings (quarterly) are held annually. These quarterly meetings are to be scheduled to review quarterly financial results and to review the quarterly reports prior to release.
- C. The members of the Committee shall be elected by the Board at the meeting of the Board following each annual meeting of stockholders and shall serve until their successors shall be duly elected and qualified or until their earlier resignation or removal. The Board shall appoint the Chair who sets the date of four regular meetings, calls special meetings as required, maintains meeting records and reports to the Board on all Committee activities.
- D. The Committee may investigate any matter within the scope of its responsibilities, may retain independent counsel or professional services, if necessary, to discharge its duties and may meet independently with members of management, independent or internal auditors or others to obtain information.

A-3		
	EXHIBIT	В
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STEWART & STEVENSON SERVICES, INC.

1996 DIRECTOR STOCK PLAN

## APRIL 8, 2002

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B-1

## TABLE OF CONTENTS

	PAGE	٤
ARTICLE	I. PURPOSE1	
ARTICLE	II. ELIGIBILITY1	
ARTICLE	III. STOCK SUBJECT TO THE PLAN	
ARTICLE	IV. DIRECTOR STOCK AWARDS	
ARTICLE	V. TERMS, CONDITIONS AND FORM OF OPTIONS       1         SECTION 5.1 NON-STATUTORY STOCK OPTIONS       2         SECTION 5.2 OPTION GRANT DATES       2         SECTION 5.3 TRANSFERABILITY       2         SECTION 5.4 VESTING AND TERM OF OPTION       2         SECTION 5.5 CHANGE OF CONTROL       2         SECTION 5.6 MANNER OF EXERCISE       3         SECTION 5.7 TERMINATION OF DIRECTORSHIP       3	
ARTICLE	VI. OPTION PRICE4	
ARTICLE	VII. VALUATION OF STOCK4	
ARTICLE	VIII. NO RIGHT TO CONTINUE AS A DIRECTOR4	
ARTICLE	IX. ADJUSTMENT TO STOCK4	
ARTICLE	X. EFFECTIVE DATE4	
ARTICLE	XI. AMENDMENT OF THE PLAN5	
ARTICLE	XII. USE OF PROCEEDS5	
ARTICLE	XIII. COMPLIANCE WITH APPLICABLE LAWS	

ARTICLE	XIV.	GOVERNING	LAW	5
ARTICLE	XV.	SUCCESSORS		_

B-2

# STEWART & STEVENSON SERVICES, INC. AMENDED AND RESTATED 1996 DIRECTOR STOCK PLAN

#### ARTICLE I. PURPOSE

The purpose of this Amended and Restated 1996 Director Stock Plan (the "Plan") of Stewart & Stevenson Services, Inc. (the "Company") is to encourage ownership in the Company by outside directors of the Company whose continued services are considered essential to the Company's continued progress, to provide them with a further incentive to continue as directors of the Company, and to increase the value of the Company.

#### ARTICLE II. ELIGIBILITY

Each director of the Company is eligible to participate in the Plan, unless he or she is an officer or employee of the Company or any subsidiary of the Company ("Eligible Director").

#### ARTICLE III. STOCK SUBJECT TO THE PLAN

The total number of the Company's authorized but unissued shares of common stock, without par value, ("Stock") with respect to which Director Stock Awards and options may be granted shall not exceed in the aggregate 350,000 shares. The class and aggregate number of shares of Stock that may be subject to Director Stock Awards and options granted under the Plan shall be subject to adjustment in accordance with Article IX. In connection with the issuance of shares of Stock under the Plan, the Company may utilize treasury shares or authorized but unissued shares. If any Director Stock Award or option under the Plan shall expire or terminate for any reason without having been exercised in full or if any Director Stock Award or option shall be forfeited, the shares subject to the unexercised or forfeited portion of such award or option shall again be available for purposes of the Plan.

#### ARTICLE IV. DIRECTOR STOCK AWARDS

On the date of each annual meeting of the Company's shareholders ("Annual Meeting") after the Effective Date (within the meaning of Article X), the Company will, without cost to the grantee and without the exercise of the discretion of any person or persons, award and issue to each Eligible Director who is elected to serve a term as a director at each such meeting and to each Eligible Director who is serving as a director for a term that continues after such meeting, that number of shares of Stock (rounded down to the nearest whole share) determined by dividing (i) the sum of \$15,000 by (ii) the fair market value (as determined in Article VII) of a share of Stock on the date of such meeting. If an Eligible Director is elected or appointed to serve a term as a director on a date other than the date of the Company's Annual Meeting and has not otherwise received a Director Stock Award for such year, the Company will, without cost to the grantee and without the exercise of the discretion of any person or persons, award and issue to such Eligible Director a prorated Director Stock Award equal to the product of (X) the quotient of \$15,000 divided by the fair market value (as determined in Article VII) of a share of Stock on the date

of such election or appointment, multiplied by (Y) the quotient of the number of days remaining until the Company's next Annual Meeting divided by 365 days. With respect to each Director Stock Award, the Eligible Director shall pay to the Company all amounts, if any, that the Company is required to collect and remit to the Internal Revenue Service or any other taxing authority as a result of such award.

B-3

#### ARTICLE V. TERMS, CONDITIONS AND FORM OF OPTIONS

Each option granted under this Plan shall be evidenced by a written agreement that shall be subject to the following terms and conditions:

SECTION 5.1 NON-STATUTORY STOCK OPTIONS. All options granted under the Plan shall be nonstatutory options, not entitled to special tax treatment under Section 422 of the Internal Revenue Code of 1986, as amended to date and as may be further amended from time to time (the "Code").

SECTION 5.2 OPTION GRANT DATES. On the date of each Annual Meeting after the Effective Date of the Plan, the Company will, without cost to the grantee and without the exercise of the discretion of any person or persons, grant to each Eligible Director who is elected to serve a term as a director at such meeting and to each Eligible Director who is serving as a director for a term that continues after such meeting, an option to acquire 5,000 shares of Stock at an exercise price determined in accordance with Article VI and subject to adjustment under Article IX; PROVIDED, that the Board of Directors may, in its discretion by majority vote, increase or decrease the number of shares subject to the aforementioned option. If an Eliqible Director is elected or appointed to serve a term as a director on a date other than the date of the Company's Annual Meeting and has not otherwise received an option to acquire shares of Stock for such year, the Company will, without cost to the grantee and without the exercise of the discretion of any person or persons, on the date of such election or appointment, grant to such Eligible Director an option to acquire 5,000 shares of Stock at an exercise price determined in accordance with Article VI and subject to adjustment under Article IX; PROVIDED, that the Board of Directors may, in its discretion by majority vote, increase or decrease the number of shares subject to such option.

Furthermore, the Board of Directors of the Company may, from time to time, deem it appropriate and may provide certain Eligible Directors with additional options to acquire Stock at an exercise price determined in accordance with Article VI and subject to adjustment under Article IX.

SECTION 5.3 TRANSFERABILITY. Each option granted under the Plan by its terms shall not be transferable by the grantee otherwise than by will or by the laws of descent and distribution or pursuant to a domestic relations order as defined by the Code or Title I of the Employee Retirement Income Security Act, or the rules thereunder.

SECTION 5.4 VESTING AND TERM OF OPTION. Options become exercisable on the first anniversary date after the date upon which the options were granted. When an option becomes exercisable, the shares may be purchased at any time, or from time to time, in whole or in part, until the option term expires; provided, however, that any option granted pursuant to the Plan shall become exercisable in full upon the death of the grantee, the failure of such grantee to stand for re-election or be re-elected, or the retirement of such grantee after serving at least 60 consecutive months on the Board of Directors. Unless terminated earlier

in accordance with the terms of the Plan, each option shall terminate upon the expiration of ten years after such option was granted.

SECTION 5.5 CHANGE OF CONTROL. In the case of any merger, exchange of shares, consolidation or combination of the Company (other than a transaction in which the holders of Stock immediately prior to the consummation thereof own 50% or more of the voting securities eligible to vote for the election of directors of the surviving entity immediately after the consummation of such transaction) all options theretofore granted and not fully exercisable shall become exercisable on the date that is 30 days prior to the record or effective date of such merger, exchange of shares, consolidation or combination.

If a tender offer or exchange offer for the Stock (other than such an offer by the Company) is commenced or if the Company shall set a record date to approve an agreement providing for a sale or other disposition of all or substantially all of the assets of the Company, all options theretofore granted and not fully exercisable shall become exercisable in full upon the commencement of such tender offer

B-4

or 30 days prior to such record date and shall remain so exercisable for a period of 60 days following such date after which they shall revert to being exercisable in accordance with their terms.

If any tender offer, exchange offer, or sale or other disposition of all or substantially all of the assets of the Company results in any grantee ceasing to be a director of the Company, then all options theretofore granted and not fully exercisable shall automatically become exercisable in full upon the termination of such person as a director.

SECTION 5.6 MANNER OF EXERCISE. Options may be exercised only by written notice to the Company, which notice must specify the date the stock option is to be exercised (such date must be on or after the date of the notice) and the number of shares of Stock covered by the exercise, accompanied by payment of the full option price of the shares covered by the options being exercised and payment of all amounts, if any, that the Company is required to collect and remit to the Internal Revenue Service or any other taxing authority as a result of such exercise. Such payment shall be made in one or a combination of the following alternative forms:

- (i) cash (including check, bank draft or money order);
- (ii) certificates, duly endorsed or accompanied by appropriate transfer instruments, representing shares of Stock previously acquired and standing in the name of the grantee, with an aggregate fair market value on the date of exercise that is equal to or less than the option price of the shares covered by the options being exercised hereunder; or
- (iii) by delivering a properly executed exercise notice together with irrevocable instructions to a broker to deliver promptly to the Company the total option price in cash.

If the grantee desires that the shares of Stock be registered in his or her name and that of another as joint tenants with rights of survivorship, he or she should so state in the notice. In no case may fewer than 100 of such shares be purchased at any one time, except to purchase a residue of fewer than 100 shares. An option may not be exercised for a fractional share.

SECTION 5.7 TERMINATION OF DIRECTORSHIP. All rights of a grantee in an option, to the extent that such rights have not been exercised, shall lapse and be forfeited one year after the termination of his or her services as a director of the Company or, if earlier, on the original expiration date of the option. In the case of retirement, whether by reason of disability or age, such grantee's option may be exercised within the period set forth in the preceding sentence by such grantee or his or her legal representative. In the case of death, such grantee's option may be exercised within the period set forth in the preceding sentence by the personal representative of the grantee's estate or by the person or persons to whom the option is transferred pursuant to the grantee's will or in accordance with the laws of descent and distribution.

#### ARTICLE VI. OPTION PRICE

The option price per share for the shares covered by each option shall be the fair market value (as determined in Article VII) of one share of Stock as of the date of grant of the option; PROVIDED, that the Board of Directors may, in its discretion by majority vote, set the option price per share for the shares covered by each option in excess of the fair market value of one share of Stock as of the date of grant of the option.

B-5

#### ARTICLE VII. VALUATION OF STOCK

For all valuation purposes under the Plan, the fair market value of a share of Stock shall be the last reported sale price as of the close of trading activity on the day for which such fair market value is to be determined, as reported on the Nasdaq National Market system, or any similar system then in use, or the principal securities exchange on which the Stock is listed on such date. If there is no trade on such day, then the last trade price on the next preceding day for which there does exist such a trade shall be determinative of fair market value.

## ARTICLE VIII. NO RIGHT TO CONTINUE AS A DIRECTOR

Neither the Plan nor the granting of a Director Stock Award or an option nor any other action taken pursuant to the Plan shall constitute or be evidence of any agreement or understanding, express or implied, that the Company will retain a director for any period of time or at any particular rate of compensation.

#### ARTICLE IX. ADJUSTMENT TO STOCK

In the event any change is made to the Stock subject to the Plan or subject to any outstanding option granted under the Plan (whether by reason of merger, exchange of shares, consolidation, reorganization, recapitalization, stock dividend, stock split, combination of shares, exchange of shares, change in corporate structure or otherwise), then appropriate adjustments shall be made to the number of shares and option price per share of Stock subject to outstanding options. The grant of Stock or options under the Plan shall not affect the right of the Company to adjust, reclassify, reorganize or otherwise change its capital or business structure or to merge, consolidate, dissolve, liquidate or sell or transfer all or any part of its business or assets.

#### ARTICLE X. EFFECTIVE DATE

The Plan originally became effective on June 10, 1997, the date of the first Annual Meeting after the adoption of the Plan by the Board of Directors of

the Company (the "Effective Date").

#### ARTICLE XI. AMENDMENT OF THE PLAN

The Board of Directors of the Company may suspend or discontinue the Plan or revise or amend it in any respect whatsoever; provided that no such amendment shall adversely affect a grantee's rights under any Director Stock Award previously issued or option previously granted without the grantee's consent.

#### ARTICLE XII. USE OF PROCEEDS

The cash proceeds received by the Company from the issuance of shares pursuant to options under the Plan shall be used for general corporate purposes.

#### ARTICLE XIII. COMPLIANCE WITH APPLICABLE LAWS

All transactions pursuant to terms of the Plan, including, without limitation, grants of Stock and grants and vesting of options, shall only be effective at such time as counsel to the Company shall have determined that such transaction will not violate federal or state securities or other laws or regulations.

#### ARTICLE XIV. GOVERNING LAW

The Plan and all determinations made and actions taken pursuant hereto shall be governed by the laws of the State of Texas and construed accordingly.

#### ARTICLE XV. SUCCESSORS

The Plan shall be binding upon the successors and assigns of the  $\operatorname{\mathsf{Company}}$  .

B-6

#### APPENDIX

STEWART & STEVENSON SERVICES, INC. 2707 NORTH LOOP WEST P.O. BOX 1637 HOUSTON, TEXAS 77251-1637

ANNUAL MEETING OF SHAREHOLDERS
TO BE HELD JUNE 11, 2002

#### Dear Shareholder:

The Annual Meeting of Shareholders of Stewart & Stevenson Services, Inc. (the "Company") will be held at 10:00 a.m. on Tuesday, June 11, 2002, in the Doubletree Hotel, 2001 Post Oak Blvd., Houston, Texas, for the following purposes:

- 1. Election of four directors to the Board of Directors.
- 2. Approval of the Amended and Restated 1996 Director Stock Plan.
- Ratification of Ernst & Young LLP as the Company's independent auditors for the fiscal year ending January 31, 2003.

Only record holders of our Common Stock at the close of business on April 24, 2002 will be entitled to vote at the meeting or any adjournment thereof.

IT IS IMPORTANT THAT YOUR SHARES BE REPRESENTED AT THE MEETING. EVEN IF YOU PLAN TO ATTEND, WE URGE YOU TO COMPLETE AND SIGN THE PROXY CARD BELOW, DETACH IT FROM THIS LETTER AND RETURN IT IN THE POSTAGE PAID ENVELOPE ENCLOSED IN THIS PACKAGE. The giving of such proxy does not affect your right to vote in person if you attend this meeting. The prompt return of your signed proxy will aid the Company in reducing the expense of additional proxy solicitation.

BY ORDER OF THE BOARD OF DIRECTORS

/s/ CARL B. KING CARL B. KING

MAY 3, 2002 SENIOR VICE PRESIDENT, SECRETARY AND GENERAL COUNSEL

DETACH PROXY CARD HERE

STEWART & STEVENSON SERVICES, INC.
ANNUAL MEETING OF SHAREHOLDERS - JUNE 11, 2002
COMMON STOCK PROXY

THIS PROXY IS SOLICITED ON BEHALF OF THE BOARD OF DIRECTORS

The undersigned hereby appoints Carl B. King and Rita M. Schaulat, and each of them, the attorneys and proxies of the undersigned (each with power to act without the other and with power of substitution) to vote, as designated on the reverse side, all shares of Common Stock, without par value, of Stewart & Stevenson Services, Inc. which the undersigned may be entitled to vote at the Annual Meeting of Shareholders to be held at the Doubletree Hotel, 2001 Post Oak Blvd., Houston, Texas at 10:00 a.m. on Tuesday, the 11th day of June, 2002 and any adjournments thereof, upon all matters which may properly come before said Annual Meeting.

THIS PROXY SHALL BE VOTED IN ACCORDANCE WITH THE INSTRUCTIONS MARKED ON THE REVERSE SIDE HEREOF. IF NO CHOICE IS MARKED, THE UNDERSIGNED GRANTS THE PROXIES DISCRETIONARY AUTHORITY WITH RESPECT TO THE ELECTION OF DIRECTORS, PROPOSAL 2 AND PROPOSAL 3. UNLESS OTHERWISE SPECIFIED, THIS PROXY WILL BE VOTED FOR THE ELECTION OF ALL NOMINEES LISTED ON THE REVERSE SIDE, FOR PROPOSAL 2 AND FOR PROPOSAL 3.

Any proxy heretofore given by the undersigned with respect to such stock is hereby revoked. Receipt of the Notice of the Annual Meeting, Proxy Statement and Annual Report to Shareholders is hereby acknowledged.

(Please sign and date proxy on reverse side and return in enclosed envelope)

STEWART & STEVENSON SERVICES, INC. P.O. BOX 11285
NEW YORK, NY 10203-0285

THE BOARD OF DIRECTORS RECOMMENDS A VOTE "FOR" THE FOLLOWING NOMINEES AND "FOR" ITEMS 2 AND 3. 1. Election of Directors FOR all nominees WITHHOLD AUTHORITY to vote listed below [ ] for all nominees listed below [ ] Nominees: Khleber V. Attwell, C. Jim Stewart III, Darvin M. Winick, PH.D, Howard Wolf (INSTRUCTIONS: TO WITHHOLD AUTHORITY TO VOTE FOR ANY INDIVIDUAL NOMINEE, MARK THE "EXCEPTIONS" BO NOMINEE'S NAME IN THE SPACE PROVIDED BELOW.) \*Exceptions \_\_\_\_\_ 2. Approval of Amended and Restated 1996 Director In their discretion the Proxies Stock Plan. upon such other matters as may meeting or any adjournment or p FOR [ ] AGAINST [ ] ABSTAIN [ ] 3. Approval of Ernst & Young LLP as independent auditors of the Company. FOR [ ] AGAINST [ ] ABSTAIN [ ] The signature on this Proxy sho shareholder's name as printed t tenancies, co-executors or co-t signing as Attorney, Executor, should give their full title. Date Share Owner sign here Co-Owner sign here \_\_\_\_\_ \_\_\_\_\_

by us will be issued as patents, or that our issued patents will afford meaningful protection against competitors. Once issued, patents are subject to challenge through both administrative and judicial proceedings in the United States and other countries. Such proceedings include re-examinations, *inter partes* reviews, post-grant reviews and interference proceedings before the U.S. Patent and Trademark Office, as well as opposition proceedings before the European Patent Office. Litigation may be required to enforce, defend or obtain our patent and other intellectual property rights. Any administrative proceeding or litigation could require a significant commitment of our resources and, depending on outcome, could adversely affect the scope, validity or enforceability of certain of our patent or other proprietary rights.

## Table of Contents

## Remodulin, Tyvaso and Orenitram Proprietary Rights

We have a number of issued patents and pending patent applications covering the stable prostacyclin analogue known as treprostinil, which is the active pharmaceutical ingredient in Remodulin, Tyvaso and Orenitram.

In January 1997, we acquired patents covering the use of treprostinil for PAH from GlaxoSmithKline PLC (formerly Glaxo Wellcome, Inc.) (Glaxo) in exchange for certain payments including a royalty on sales of any product containing treprostinil. All of these patents expired in October 2014, as did our royalty payment obligation to Glaxo.

In October 1997, we filed patent applications for a new synthesis method for treprostinil in the United States, Europe and various other countries. These applications resulted in the grant of three patents in the United States, all of which expire in October 2017, as well as patents granted in a number of other countries which expire in October 2018.

We continue to conduct research into new methods to synthesize treprostinil and have filed a number of additional patent applications relating to production of treprostinil, several of which have already been granted in the United States. One such patent was granted, expiring in 2028, and is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book (see *Orange Book* below), for Remodulin, Tyvaso and Orenitram.

In addition to the treprostinil patents noted above, we have other patents specific to our individual treprostinil-based products, including the following:

*Remodulin.* We have been granted three U.S. patents covering an improved diluent for Remodulin, which expire in 2028 and 2029. We have another patent covering intravenous administration of Remodulin with certain diluents, which expires in 2024. All four of these patents are listed in the Orange Book.

*Tyvaso.* We have been granted two U.S. patents, as well as patents in other countries, for Tyvaso that cover methods of treating PAH by inhaled delivery. These patents will expire in the United States in 2018 and in various countries throughout the world in 2020.

*Orenitram.* Our patents for Orenitram cover methods of use for treating PAH, orally administered formulations, controlled moisture storage and production methods, as well as those covering controlled release formulations licensed to us by Supernus Pharmaceuticals Inc. (Supernus). These patents will expire in the United States between 2024 and 2031 and in various countries throughout the world between 2024 and 2027.

We have additional pending U.S. and international patent applications relating to Remodulin, Tyvaso and Orenitram.

#### Orange Book

In seeking approval of a drug through an NDA or BLA or upon issuance of new patents following approval of an NDA or BLA, applicants are required to submit to the FDA each patent that has claims covering the applicant's product or a method of using the product. Each of the patents submitted is then published in the Orange Book. See *Governmental Regulation Hatch-Waxman Act* below for further details. Remodulin currently has six unexpired Orange Book-listed patents with expiration dates ranging from 2017 to 2029. Tyvaso currently has four unexpired Orange Book listed patents with expiration dates ranging from 2017 to 2028. Orenitram currently has nine unexpired Orange Book listed patents with expiration dates ranging from 2017 to 2031. Additional patent applications are pending, and if granted, may be eligible for listing in the Orange Book.

## **Table of Contents**

# Regulatory Exclusivity

In June 2010, the FDA granted orphan drug designation for Tyvaso. This designation confers an exclusivity period through July 2016, during which the FDA may not approve any application to market the same drug for the same indication, except under limited circumstances. As a result of FDA approval of our NDA for Orenitram as a new dosage form, Orenitram has three years of market exclusivity for PAH expiring in December 2016. A request for orphan drug designation for Orenitram is pending with the FDA.

Remodulin was formerly protected in the EU by data protection regulations, which prevent the grant of an abbreviated marketing approval for a product containing treprostinil for the treatment of PAH for a period of either six or ten years from the date of the grant of the first marketing authorization in the EU. In those countries where protection runs for six years, that period expired prior to 2015, while in those countries where protection runs for ten years, that period expired in February 2015.

# Generic Competition

In September 2015, we settled litigation with Sandoz relating to Sandoz's ANDA seeking FDA approval to market a generic version of Remodulin before the expiration of certain of our U.S. patents in October 2017, September 2028, December 2028, and March 2029. Under the terms of this settlement, Sandoz will be permitted to market its generic version of Remodulin in the United States beginning in June 2018, although Sandoz may be permitted to enter the market earlier under certain circumstances. We also recently settled litigation with Teva relating to a similar ANDA to market a generic version of Remodulin. That settlement permits Teva to market its generic version of Remodulin in the United States beginning in December 2018, although Teva may be permitted to enter the market earlier under certain circumstances. We are engaged in litigation against Watson Laboratories, Inc. (Watson), contesting its ANDA to market a generic version of Tyvaso before the expiration of certain of our U.S. patents in November 2018 and December 2028. Finally, in October 2015 SteadyMed Ltd. (SteadyMed) filed a petition for inter partes review seeking to invalidate one of our patents that expires in December 2028 and covers a method of making treprostinil, which is the active ingredient in Remodulin, Tyvaso and Orenitram. SteadyMed has announced that it is developing a product called Trevvent, which is a single-use, pre-filled pump intended to deliver a two-day supply of treprostinil subcutaneously using SteadyMed's PatchPump® technology. In January 2016, SteadyMed announced that Trevyent has been granted orphan drug designation by the FDA for the treatment of PAH. These matters are discussed further in *Item 3 Legal Proceedings* of this Annual Report on Form 10-K, and in Note 19 Litigation, to our consolidated financial statements included with this Annual Report on Form 10-K. In February 2016, we received notice that Actavis Laboratories FL, Inc. (Actavis) filed an ANDA seeking FDA approval to market a generic version of the 2.5 mg strength of Orenitram. For further details, please see Part II, Item 9B Other Information.

As a result of our settlements with Sandoz and Teva, we expect to see generic competition from these companies for Remodulin beginning in June 2018 and December 2018, respectively. This increased competition could reduce our sales and profits. In addition, while we intend to vigorously enforce our intellectual property rights relating to Tyvaso and Orenitram, we may not prevail in defending our patent rights, and additional challenges from other ANDA filers or other challengers may surface with respect to these products. Our patents could be invalidated, found unenforceable or found not to cover one or more generic forms of Remodulin, Tyvaso or Orenitram. If any ANDA filer receives approval to sell a generic version of Remodulin, Tyvaso or Orenitram and/or prevail in any patent litigation, the affected product(s) would become subject to increased competition, which could reduce our sales and profits.

## **Table of Contents**

Certain patents for Revatio, a PDE-5 inhibitor marketed by Pfizer for treatment of PAH, expired in 2012, leading several manufacturers to launch generic formulations of sildenafil citrate, the active ingredient in Revatio. Generic sildenafil's lower price relative to Adcirca could lead to pressure from payers to use generic products within the same class of therapy initially, which could erode Adcirca's market share and limit its potential sales. Although we believe Adcirca's once-daily dosing regimen provides a significant competitive advantage over generic sildenafil's multiple dosing regimen, government payers and private insurance companies may favor the use of less expensive generic sildenafil over Adcirca. Thus far, we have not observed any measurable impact of generic sildenafil on sales of Adcirca; however, circumstances could change over time and our revenues could be adversely impacted. The U.S. patent for Adcirca for the treatment of pulmonary hypertension will expire in November 2017, following which we expect to see generic competition for Adcirca.

Patent expiration and generic competition for any of our commercial PAH products could have a significant, adverse impact on our revenues and profits, and is inherently difficult to predict. For additional discussion, refer to the risk factor entitled, *Our intellectual property rights may not effectively deter competitors from developing competing products that, if successful, could have a material adverse effect on our revenues and profits*, contained in *Item 1A Risk Factors* included in this Annual Report on Form 10-K.

## Supernus License

In 2006, we entered into an exclusive license agreement with Supernus to use certain of its technologies in producing Orenitram. Under the agreement, we paid Supernus certain amounts upon the achievement of specified milestones based on the development and commercial launch of Orenitram for PAH, and we would be obligated to make additional milestone payments if we develop Orenitram for a second indication. In addition, the agreement provides that we will pay a single-digit royalty based on net worldwide sales. This royalty will be paid for approximately twelve years commencing with the first product sale and is subject to adjustments as specified in the agreement. The royalties commenced in the second quarter of 2014 with the first sale of Orenitram.

# Lilly Agreements Related to Adcirca

In 2008, we entered into several agreements with Lilly regarding Adcirca, including a license agreement and a manufacturing and supply agreement.

# License Agreement

Under the terms of the license agreement, Lilly granted us an exclusive license for the right to develop, market, promote and commercialize Adcirca for the treatment of pulmonary hypertension in the United States. We agreed to pay Lilly royalties equal to five percent of our net product sales of Adcirca, as a pass through of Lilly's third-party royalty obligations, for so long as Lilly is required to make such payments.

Lilly retained the exclusive rights to develop, manufacture and commercialize pharmaceutical products containing tadalafil, the active pharmaceutical ingredient in Adeirca, for the treatment of pulmonary hypertension outside of the United States and for the treatment of other diseases worldwide. Lilly retained authority for all regulatory activities with respect to Adeirca and for setting the wholesale price of Adeirca, which has been and is expected to continue to be at price parity with Cialis.

The license agreement will continue in effect until the later of: (1) expiration, lapse, cancellation, abandonment or invalidation of the last claim to expire within a Lilly patent covering the commercialization of Adcirca for the treatment of pulmonary hypertension in the United States; or

## Table of Contents

(2) expiration of any government-conferred exclusivity rights to use Adcirca for the treatment of pulmonary hypertension in the United States.

We have the right to terminate the license agreement upon six months written notice to Lilly. Lilly has the right to terminate in the event of a change of control of our company. Either party may terminate upon a material breach by the other party of the license agreement or the manufacturing and supply agreement, described above.

The U.S. patent for Adcirca for the treatment of pulmonary hypertension will expire in November 2017.

Manufacturing and Supply Agreement

Under the terms of the manufacturing and supply agreement, Lilly agreed to manufacture Adcirca and distribute it on our behalf via its pharmaceutical wholesaler network, in the same manner that it distributes its own pharmaceutical products. Under the terms of this agreement, we take title to Adcirca upon its manufacture by Lilly. Adcirca is shipped to customers, generally pharmaceutical wholesalers, in accordance with customers' purchase orders received by Lilly. Lilly invoices and collects amounts due from the customer subject to customary discounts and rebates, if any, and remits the collections to us. Although Lilly is providing these services on our behalf, we maintain the risk of loss as it pertains to inventory, product returns and nonpayment of sales invoices. The manufacturing and supply agreement will continue in effect until expiration or termination of the license agreement.

We also agreed to purchase Adcirca at a fixed manufacturing cost. The agreement provides a mechanism, generally related to the increase in the national cost of pharmaceutical manufacturing, pursuant to which Lilly may raise the manufacturing cost of Adcirca.

# Unituxin Proprietary Rights

In 2010, we entered into a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute (NCI) of the United States National Institutes for Health (NIH) to collaborate on the late-stage development and regulatory approval process for Unituxin for children with high-risk neuroblastoma and patients with other forms of cancer. In lieu of a royalty payment to the NCI, we have an ongoing obligation to provide the NCI with Unituxin for its studies free of charge. We previously received orphan drug designation for Unituxin from both the FDA and the EMA. Orphan designation, coupled with FDA approval of our BLA in March 2015, confers an exclusivity period through March 2022, during which the FDA may not approve any application to market the same drug for the same indication, except in limited circumstances. For further details, refer to the section above entitled *Products to Treat Cancer Unituxin*.

# Medtronic Agreement

In 2009, we entered into an exclusive agreement with Medtronic, which was amended in 2011, to collaborate on the development and commercialization of Medtronic's proprietary intravascular infusion catheter to be used with Medtronic's Synchromed II implantable infusion pump and related infusion system components (together referred to as the Remodulin Implantable System) in order to deliver Remodulin for the treatment of PAH in the United States, United Kingdom, Canada, France, Germany, Italy and Japan. Under the amended agreement, we have been working together at our expense to develop the Remodulin Implantable System, conduct a clinical trial (which was completed in 2013) and obtain regulatory approval for the use of Remodulin with the Remodulin Implantable System. If this development program is successful, our agreement provides that, upon commercialization, we will purchase infusion pumps and supplies from Medtronic and will also pay a royalty to Medtronic based on net product sales of Remodulin for use in the Remodulin Implantable System within the exclusive territories, subject to certain adjustments specified in the agreement. The

## Table of Contents

Remodulin Implantable System will be exclusive to Remodulin so long as we purchase a minimum percentage of our annual requirement for implantable pump systems from Medtronic. We will be solely responsible for all marketing and promotion of the Remodulin Implantable System for the delivery of Remodulin for the treatment of PAH in the exclusive territories. For further details, refer to the section above entitled *Products to Treat Cardiopulmonary Diseases Pulmonary Arterial Hypertension Remodulin Remodulin Implantable System*.

## Toray Amended License Agreement

In 2000, we licensed from Toray the exclusive right to develop and market beraprost for cardiovascular indications. Beraprost is a chemically stable oral prostacyclin analogue in a sustained release formulation, which is approved to treat PAH in Japan and certain other countries. This license gives us exclusive rights to develop beraprost and its variants (including esuberaprost) throughout North America, Europe, and certain other territories. We are currently developing esuberaprost under this license agreement.

Pursuant to a March 2007 amendment to our license agreement with Toray, we issued 200,000 shares of our common stock to Toray. Toray has the right to request that we repurchase these shares (which have since split into 400,000 shares) upon 30 days prior written notice at the price of \$27.21 per share. The 2007 amendment also provided for certain milestone payments during the development period and upon receipt of regulatory approval for beraprost in the United States or the EU.

In 2011, we amended our license agreement with Toray to reduce the royalty rates in exchange for a total of \$50.0 million in equal, non-refundable payments to Toray over the five-year period ending in 2015. As of December 31, 2015, this obligation was fully satisfied. Toray has the right to terminate the license agreement in the event of a change of control of our company under certain circumstances. For further details, refer to the section above entitled *Products to Treat Cardiopulmonary Diseases Pulmonary Arterial Hypertension Esuberaprost.* 

#### **DEKA Agreement**

In December 2014, we entered into an exclusive agreement with DEKA to develop a pre-filled, semi-disposable pump system for subcutaneous delivery of Remodulin. Under the terms of the agreement, we are funding the development costs related to the semi-disposable pump system and will pay product fees and a single-digit royalty to DEKA based on commercial sales of the system and the Remodulin sold for use with the system. Our goal is to be in a position to receive FDA approval for this delivery system by the end of 2018.

## Other

We are party to various other license agreements relating to therapies and technologies under development. These license agreements require us to make payments based on a percentage of sales if we are successful in commercially developing these therapies, and may require other payments upon the achievement of certain milestones.

## **Research & Development Expenditures**

We are engaged in research and development and have incurred substantial expenses for these activities. These expenses generally include the cost of acquiring or inventing new technologies and products, as well as new product development (both preclinical and clinical studies and manufacturing cost for unapproved products). Research and development expenses during the years ended December 31, 2015, 2014 and 2013 totaled approximately \$245.1 million, \$242.5 million and \$299.3 million, respectively. See *Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations Major Research and Development Projects* for additional information

## Table of Contents

regarding expenditures related to major research and development projects. Research and development expense is significantly impacted by fluctuations in our stock price, due to the cash payment obligations created by our share-based compensation programs. For further details, see *Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations Operating Expenses Share-Based Compensation.* 

## **Production and Supply**

We produce our primary supply of Remodulin, Tyvaso, Orenitram and Unituxin at our own facilities. In particular, we synthesize treprostinil, the active ingredient in Remodulin and Tyvaso, and treprostinil diolamine, the active ingredient in Orenitram, at our facility in Silver Spring, Maryland. We also produce finished Tyvaso, Remodulin, and Unituxin at our Silver Spring facility. We produce Orenitram and we package, warehouse and distribute Remodulin, Tyvaso, Orenitram and Unituxin, at our facility in Research Triangle Park, North Carolina.

We maintain a two-year inventory of Remodulin, Tyvaso and Orenitram based on expected demand, and we also contract with third-party contract manufacturers to supplement our capacity, in order to mitigate the risk that we might not be able to produce sufficient quantities to meet patient demand. For example, Baxter Pharmaceutical Solutions, LLC (Baxter) is approved by the FDA, the EMA and various other international regulatory agencies to produce Remodulin for us. In the case of Tyvaso, we rely on Catalent Pharma Solutions, Inc. (Catalent) to serve as an additional producer of Tyvaso, and we rely entirely on Minnetronix Inc. to manufacture the nebulizer used in our Tyvaso Inhalation System. We are working to obtain FDA approval of third party contract manufacturers to serve as additional producers of Orenitram and Unituxin.

Although we believe that additional third parties could provide similar products, services and materials, there are few companies that could replace our existing third-party producers and suppliers. A change in supplier or producer could cause a delay in the production, distribution and research efforts associated with our respective products or result in increased costs. See also *Item 1A Risk Factors* included in this Annual Report on Form 10-K.

#### Competition

Many drug companies engage in research and development to commercialize products to treat cardiovascular diseases and cancer. For the treatment of PAH, we compete with many approved products in the United States and the rest of the world, including the following:

Flolan, Veletri and generic epoprostenol. Flolan (epoprostenol) is a prostacyclin that is delivered by intravenous infusion. Glaxo began marketing Flolan in the United States in 1996, and the generic exclusivity period for Flolan expired in 2007. In 2008, the FDA approved Teva's version of generic epoprostenol for the treatment of PAH. In 2010, Actelion commenced sales of Veletri, which is another version of intravenous epoprostenol;

*Ventavis and Ilomedin*®. Approved in 2004 in the United States and in 2003 in Europe, Ventavis (iloprost) is an inhaled prostacyclin analogue. Ventavis is currently marketed by Actelion in the United States and by Bayer in Europe. Iloprost is also marketed by Bayer in certain countries outside the United States in an intravenous form known as Ilomedin;

*Tracleer*. Tracleer (bosentan), an oral ETRA therapy for the treatment of PAH, was approved in 2001 in the United States and in 2002 in Europe. Tracleer is marketed worldwide by Actelion;

Letairis. Approved in 2007 in the United States, Letairis (ambrisentan) is an oral ETRA therapy marketed by Gilead for the treatment of PAH. In 2008, Glaxo received marketing authorization from the EMA for Letairis in Europe, where it is known as Volibris®;

## Table of Contents

Revatio and generic sildenafil citrate. Approved in 2005 in the United States, Revatio (sildenafil citrate) is an oral PDE-5 inhibitor therapy marketed by Pfizer. Revatio contains sildenafil citrate, the same active ingredient as Viagra. In the fourth quarter of 2012, several companies began marketing generic formulations of sildenafil citrate;

*Opsumit.* Approved in October 2013 in the United States and December 2013 in the EU, Opsumit (macitentan) is an oral ETRA marketed by Actelion for the treatment of PAH;

*Adempas*®. Approved in August 2013 in the United States and March 2014 in the EU, Adempas (riociguat) is a soluble guanylate cyclase stimulator, which targets a similar vasodilatory pathway as PDE-5 inhibitors and is approved for chronic thromboembolic pulmonary hypertension and PAH. Adempas is an oral therapy marketed by Bayer; and

*Uptravi*. Approved in the United States in December 2015, Uptravi (selexipag) is an oral IP prostacyclin receptor agonist marketed by Actelion. Actelion submitted an MAA for EMA approval of Uptravi in December 2014, and in January 2016 received a positive opinion from the Committee for Medicinal Products for Human Use recommending European Commission approval for Uptravi. Actelion also has applications pending in various other jurisdictions. Nippon Shinyaku Co., Ltd. holds the right to market Uptravi in Japan, where it submitted an NDA in January 2016.

There are also a variety of investigational PAH therapies in the later stages of development, including the following:

*Ralinepag*, an oral IP prostacyclin receptor agonist being developed by Arena Pharmaceuticals, Inc. (Arena). Arena commenced a phase II clinical trial of ralinepag in 2014; and

*Trevyent*, a formulation of treprostinil being developed by SteadyMed Ltd. (SteadyMed) for delivery via its pre-filled, disposable PatchPump®. SteadyMed announced that it plans to submit an NDA and MAA for Trevyent in the second half of 2016. In January 2016, SteadyMed announced that Trevyent has been granted orphan drug designation by the FDA for the treatment of PAH.

Oral non-prostacyclin therapies (such as PDE-5 inhibitors and ETRAs) are commonly prescribed as first-line treatments for the least severely ill PAH patients (NYHA Class II patients). As patients progress in their disease severity (NYHA Class III and IV), less convenient approved therapies, such as inhaled prostacyclin analogues (such as Tyvaso) or infused prostacyclin analogues (such as Remodulin) are commonly added. Orenitram is the first approved oral prostacyclin therapy for PAH in the United States. We anticipate that it will face competition with existing oral PAH therapies, and will be regarded as a less invasive and more convenient alternative therapy to Tyvaso and Remodulin. The use of available oral therapies could delay many patients' need for inhaled or infused prostacyclin therapy. As a result, the availability of oral therapies affects demand for our inhaled and infused products.

Orenitram faces competition from Uptravi, which is indicated to delay disease progression and reduce the risk of hospitalization for PAH. This indication may provide a competitive advantage against Orenitram, which is indicated to improve exercise capacity. As noted above, however, Uptravi is an oral IP prostacyclin receptor agonist, a new class of therapy that addresses PAH through the prostacyclin pathway. While prostacyclin analogues such as Orenitram broadly mimic the effect of prostacyclin, IP prostacyclin receptor agonists bind selectively to the IP receptor, one of several prostacyclin receptors. In addition, Orenitram's label allows physicians flexibility to titrate each patient's dosing up to a level according to tolerability, without any stated maximum. By contrast, Uptravi's label limits uptitration to a specific maximum dose.

## Table of Contents

We will also likely face competition from generic pharmaceutical companies in the future. For example, two generic companies filed ANDAs requesting FDA approval to market a generic version of Remodulin. We settled patent litigation with both companies, and our settlement agreements will allow Sandoz and Teva to launch generic versions of Remodulin in June 2018 and December 2018, respectively. Generic companies have filed ANDAs requesting FDA approval to market generic versions of Tyvaso and Orenitram. For details, see the sections below entitled *Governmental Regulation Hatch-Waxman Actitem 3 Legal Proceedings*, and Part II, Item 9B Other Information. In addition, certain Revatio patents expired in 2012, leading several manufacturers to launch generic formulations of sildenafil citrate, which physicians could prescribe for the treatment of PAH. Generic sildenafil citrate's lower price, relative to Adcirca, could erode Adcirca's market share and limit its growth potential. Although we believe Adcirca's once-daily dosing regimen is an appealing alternative to generic sildenafil citrate's dosing regimen of three times per day, we expect government payers and private insurance companies to favor over time the use of the less expensive generic sildenafil citrate instead of Adcirca. The U.S. patent for Adcirca for the treatment of pulmonary hypertension will expire in November 2017, following which we expect to see generic competition for Adcirca.

We compete with the developers, manufacturers and distributors of all of the PAH products noted above for customers, funding, access to licenses, personnel, third-party collaborators, product development and commercialization. Almost all of these companies have substantially greater financial, marketing, sales, distribution and technical resources, and more experience in research and development, product development, manufacturing and marketing, clinical trials and regulatory matters, than we have.

## **Governmental Regulation**

# Pharmaceutical Product Approval Process

The research, development, testing, manufacture, promotion, marketing, distribution, sampling, storage, approval, labeling, record keeping, post-approval monitoring and reporting, and import and export of pharmaceutical products (drugs or biological products, hereinafter collectively drugs) are extensively regulated by governmental agencies in the United States and in other countries. In the United States, failure to comply with requirements under the Federal Food, Drug, and Cosmetic Act (FDC Act), the Public Health Service Act (PHSA), and other federal statutes and regulations, may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending NDAs or BLAs, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution.

Satisfaction of FDA pre-market approval requirements typically takes many years, and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease. Drugs are subject to rigorous regulation by the FDA in the United States, the EMA in the EU and similar regulatory authorities in other countries. The steps ordinarily required before a new drug may be marketed in the United States, which are similar to steps required in most other countries, include:

Preclinical laboratory tests, preclinical studies in animals, formulation studies and the submission to the FDA of an
investigational new drug application (IND) for a new drug, which must become effective before clinical testing may
commence;

Clinical studies in healthy volunteers;

Clinical studies in patients to explore safety, efficacy and dose-response characteristics;

Adequate and well-controlled clinical trials to establish the safety and efficacy of the drug for each indication;

22

## Table of Contents

The submission of an NDA or BLA to the FDA; and

FDA review and approval of the NDA or BLA prior to any commercial sale or shipment of the drug.

Preclinical tests include laboratory evaluation of product chemistry and formulation, as well as animal studies to explore toxicity and for proof-of-concept. The conduct of the preclinical tests must comply with federal regulations and requirements including good laboratory practices. In the United States, the results of preclinical testing are submitted to the FDA as part of an IND, along with other information including information about product chemistry, manufacturing and controls and a proposed clinical trial protocol. Long-term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted. Absent FDA objection within 30 days after submission of an IND, the IND becomes effective and the clinical trial proposed in the IND may begin. At any time during this 30-day period or at any time thereafter, the FDA may halt, temporarily or permanently, a clinical trial. The IND process may be extremely costly and may substantially delay development of our products. Moreover, positive results of preclinical tests will not necessarily indicate positive results in clinical trials.

Clinical trials involve the administration of the investigational new drug or biologic to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (1) in compliance with federal regulations; (2) in compliance with good clinical practices (GCP), an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors; and (3) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary or permanent discontinuation of a clinical trial at any time or impose other sanctions if it believes that the clinical trial is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The study protocol and informed consent information for patients in clinical trials must also be approved by an institutional review board (IRB). An IRB may also require the clinical trial at a site to be halted temporarily or permanently for failure to comply with the IRB's requirements, or may impose other conditions.

Clinical trials in support of an NDA or a BLA are typically conducted in sequential phases, but the phases may overlap. During phase I, the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence on effectiveness. Phase II usually involves studies in a limited patient population to assess the efficacy of the drug in specific, targeted indications, assess tolerance and optimal dosage and identify possible adverse effects and safety risks. If a compound is found to be potentially effective and to have an acceptable safety profile in phase II evaluations, then a meeting may be requested at the end of phase II to determine the safety of proceeding to phase III. Phase III trials, also called pivotal studies, major studies or advanced clinical trials, are undertaken to demonstrate clinical efficacy and safety in a larger number of patients, typically at geographically diverse clinical study sites, and to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. Phase IV studies are often conducted following marketing approval, in order to meet regulatory requirements or to provide additional data relating to the use of the drug.

After successful completion of the required clinical testing, an NDA or a BLA is typically submitted to the FDA in the United States, and an MAA is typically submitted to the EMA in the EU. FDA approval of the NDA or BLA is required before marketing of the product may begin in the United States. The NDA or BLA must include the results of all preclinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls.

## Table of Contents

The cost of preparing and submitting an NDA or BLA is substantial. Under federal law, the submission of most NDAs and BLAs is additionally subject to a substantial application fee, currently exceeding \$2.3 million, and the manufacturer and/or sponsor of an approved NDA or BLA is also subject to annual product and establishment fees, currently exceeding \$114,000 per product and \$585,000 per establishment. These fees are typically increased annually. However, the application fees may be waived for orphan drugs if certain requirements are met.

The FDA has 60 days from its receipt of an NDA or a BLA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA may instead ask for additional information, in which case, the application must be amended and resubmitted with the requested information. The FDA has agreed to certain performance goals in the review of NDAs. Most such applications for non-priority drugs are reviewed within ten to twelve months, while most applications for priority review drugs are reviewed in six to eight months. Priority review can be applied to drugs that the FDA determines offer major advances in treatment, or provide a treatment where no adequate therapy exists. For biologics, priority review is further limited to drugs intended to treat a serious or life-threatening disease. The review process may be extended by the FDA for three additional months to consider certain information submitted during FDA review, including information intended to clarify information already provided or to address any deficiencies identified in the submission. The FDA may also refer applications for novel pharmaceutical products or pharmaceutical products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. During the review process, the FDA also reviews the drug's product labeling to ensure that appropriate information is communicated to health care professionals and consumers. In addition, before approving an NDA or a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless compliance with the FDA's current Good Manufacturing Practices (cGMP) and GCP is satisfactory and the NDA or BLA contains data that provide substantial evidence that the pharmaceutical product is safe and effective for purposes of the indication studied.

In the United States, after the FDA evaluates the NDA or BLA and the manufacturing facilities, the FDA may issue either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those conditions have been addressed to the FDA's satisfaction in a resubmission of the NDA or BLA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. A Class 1 resubmission may contain only limited information such as labeling, safety updates, stability updates, or minor analysis updates or clarifying information and is subject to a two-month review period. All other resubmissions are categorized as Class 2 and are subject to a six-month review period. Even after such a resubmission, the FDA may decide that the application does not satisfy the regulatory criteria for approval.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA or BLA approval, the FDA may require a risk evaluation and mitigation strategy (REMS) to help ensure that the benefits of the drug outweigh the potential risks. A REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use (ETASU). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the drug. To continue marketing our products

## **Table of Contents**

after approval, applicable regulations require us to maintain a positive risk-benefit profile, maintain regulatory applications through periodic reports to regulatory authorities, fulfill pharmacovigilance requirements, maintain manufacturing facilities according to cGMP requirements, and successfully complete regulatory agency inspections, among other requirements. Our manufacturing facilities are subject to continual review and periodic inspections. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

#### Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA-regulated drugs and other products are required to register and disclose certain clinical trial information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial. This clinical trial information is then made public as part of the sponsor's registration. Sponsors are also obligated to disclose the results of their clinical trials after completion. Competitors may use this publicly-available information to gain knowledge regarding the progress of development programs.

## **Orphan Drugs**

Under the Orphan Drug Act, an applicant can request the FDA to designate a product as an "orphan drug" in the United States if the drug is intended to treat a rare disease or condition affecting fewer than 200,000 people in the United States. Orphan drug designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first NDA or BLA applicant to receive orphan drug designation and FDA approval for a particular active ingredient to treat a particular disease via a particular delivery method is entitled to a seven-year exclusive marketing period in the United States. During the seven-year period, the FDA may not approve any other application to market the same drug for the same disease, except in limited circumstances such as (1) a showing of clinical superiority to the product with orphan drug exclusivity, meaning that it has greater effectiveness or safety, or provides a major contribution to patient care (such as a change in delivery system); or (2) or the inability of the NDA or BLA holder for the product with orphan drug exclusivity to assure availability of sufficient quantities of the drug to meet the needs of patients with the rare disease or condition. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA or BLA application user fee.

The FDA granted orphan drug designation for the active ingredient treprostinil for the treatment of PAH as a continuous infusion. However, this designation does not preclude us from seeking orphan drug designation for other treprostinil formulations or routes of administration to treat PAH, or for treprostinil used to treat other orphan diseases. In order for the FDA to grant orphan drug designation for other formulations or routes of administration of treprostinil to treat PAH, we must demonstrate that such new formulation or route of administration is clinically superior to the formulation or route of administration previously granted orphan drug designation. The FDA has granted orphan drug designation for Tyvaso and Unituxin. A request for orphan drug designation for Orenitram is pending.

# Pediatric Information

Under the Pediatric Research Equity Act of 2007 (PREA), NDAs, BLAs and supplements to NDAs and BLAs must contain data to assess the safety and effectiveness of the drug for the claimed indication(s) in all relevant pediatric subpopulations and to support dosing and administration for each such pediatric subpopulation for which the drug is safe and effective. The FDA may grant deferrals for

## **Table of Contents**

submission of data or full or partial waivers. Unless otherwise required by regulation, the PREA does not apply to any drug for an indication for which orphan drug designation has been granted.

The Best Pharmaceuticals For Children Act (BPCA) provides NDA holders a six-month extension of any exclusivity, patent or non-patent, for a drug if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the requested time frame. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

#### Hatch-Waxman Act

The Hatch-Waxman Act (also known as the Drug Price Competition and Patent Term Restoration Act) was passed in 1984 to encourage research and development of new drugs and competition between brand and generic pharmaceutical companies. It created a faster approval process for generic drugs, called the ANDA, while providing protection to brand pharmaceuticals by extending their patent protection, in some cases, to compensate for patent life lost during the product development and approval process and providing periods of market exclusivity to encourage continuing research on, for example, new uses, strengths or dosage forms for existing drugs.

In seeking approval of a drug through an NDA, applicants are required to submit to the FDA each patent whose claims cover the applicant's product or FDA-approved method of using this product. Upon approval of a drug, each of the patents listed in the application is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an ANDA. Generally, an ANDA provides for marketing of a drug product that has the same active ingredients in the same strength(s), route of administration, and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. ANDA applicants are not required to conduct or submit results of preclinical or clinical tests to prove the safety or effectiveness of their drug product, other than the requirement for bioequivalence testing. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that: (1) the required patent information has not been filed; (2) the listed patent has expired; (3) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patent is invalid or will not be infringed by the new product. A certification that the new product will not infringe the already approved product's listed patents or that such patents are invalid is called a Paragraph IV certification. If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired. Alternatively, for a patent covering an approved method of use, an ANDA applicant may submit a statement to the FDA that the company is not seeking approval for the covered use.

If the ANDA applicant has submitted a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA 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 applicant.

## Table of Contents

The ANDA application also will not receive approval until any non-patent exclusivity, such as exclusivity for obtaining approval of an NDA for a new chemical entity, has expired. Federal law provides a period of five years following approval of a drug containing no previously approved active moiety, during which ANDAs for generic versions of those drugs cannot be submitted unless the submission contains a Paragraph IV certification, in which case the submission may be made four years following the original product approval. Following approval of an application to market a drug that contains previously approved active ingredients in a new dosage form, route of administration or combination, or for a new condition of use that was required to be supported by new clinical trials conducted by or for the sponsor, the FDC Act provides for an exclusivity period of three years, during which the FDA cannot grant effective approval of an ANDA for such new condition of use, dosage form or strength that meets certain statutory requirements. Both of the five-year and three-year exclusivity periods, as well as any unexpired patents listed in the Orange Book for the listed drug, can be extended by six months if the FDA grants the NDA sponsor a period of pediatric exclusivity based on studies submitted by the sponsor in response to a written request.

The Hatch-Waxman Act provides that patent terms may be extended to compensate for some of the patent life that is lost during the FDA regulatory review period for a product. This extension period would generally be one-half the time between the effective date of an IND and the submission date of an NDA, plus all of the time between the submission date of an NDA and its approval, subject to a maximum extension of five years. Similar patent term extensions are available under European laws. Following FDA approval, we filed a patent term extension application with the United States Patent and Trademark Office for our patent covering the method of treating PAH using treprostinil. The application was approved in February 2005 with the maximum patent term extension of five years, and the patent expired in October 2014.

We have received Paragraph IV certification letters from Watson and Actavis advising that they have submitted ANDAs to the FDA requesting approval to market generic versions of Tyvaso and Orenitram, respectively. We have also settled litigation relating to Paragraph IV certification letters from Sandoz and Teva advising that each has submitted an ANDA to the FDA requesting approval to market generic versions of Remodulin. Under our settlement agreements with Sandoz and Teva, they will be permitted to market their generic versions of Remodulin in the Unites States beginning in June 2018 and December 2018 respectively, or earlier in certain circumstances. For further details, please see Note 19 Litigation, to our consolidated financial statements [Item 3 Legal Proceedings and Part II, Item 9B Other Information.

# Section 505(b)(2) New Drug Applications

Most drug products (other than biological products) obtain FDA marketing approval pursuant to an NDA submitted under Section 505(b)(1) of the Food, Drug and Cosmetic Act (FDCA), or an ANDA. A third alternative is a special type of NDA submitted under Section 505(b)(2) of the FDCA, commonly referred to as a Section 505(b)(2) NDA, which enables the applicant to rely, in part, on the FDA's finding of safety and efficacy data for an existing product, or published literature, in support of its application.

Section 505(b)(2) NDAs may provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved products. Section 505(b)(2) permits the filing of an NDA in which the applicant relies, at least in part, on information from studies made to show whether a drug is safe or effective that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use. A Section 505(b)(2) applicant may eliminate the need to conduct certain preclinical or clinical studies, if it can establish that reliance on studies conducted for a previously-approved product is scientifically appropriate. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product candidate for all or some of the labeled indications for which

## Table of Contents

the referenced product has been approved, as well as for any new indication for which the Section 505(b)(2) NDA applicant has submitted data.

To the extent that the Section 505(b)(2) applicant is relying on prior FDA findings of safety and efficacy, the applicant is required to certify to the FDA concerning any patents listed for the previously approved product in the Orange Book to the same extent that an ANDA applicant would. Thus, approval of a Section 505(b)(2) NDA can be delayed until all the listed patents claiming the referenced product have expired, until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired, and, in the case of a Paragraph IV certification and subsequent patent infringement suit, until the earlier of 30 months, settlement of the lawsuit or a decision in the infringement case that is favorable to the Section 505(b)(2) applicant.

#### Other Regulatory Requirements

Once an NDA or a BLA is approved, the product will be subject to continuing regulations. For instance, the FDA closely regulates the post-approval marketing, labeling and advertising of prescription drugs, including the standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. Pharmaceutical products may be marketed only for their approved indications and in accordance with the provisions of their approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting promotion of off-label uses, and a company that is found to have engaged in off-label promotion may be subject to significant liability.

Certain changes to the conditions established in an approved application, including changes in indications, labeling, equipment, or manufacturing processes or facilities, will require submission and FDA approval of an NDA or BLA or supplement thereto before the change can be implemented. An NDA or BLA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing supplements as it does in reviewing NDAs or BLAs.

Adverse event reporting and submission of periodic reports continue to be required following FDA approval of an NDA or a BLA. The FDA also may require post-marketing testing, including phase IV clinical studies, risk minimization action plans, and surveillance to monitor the effects of an approved product or may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control as well as drug manufacture, packaging, and labeling procedures must continue to conform to cGMP requirements. Manufacturers and certain of their contractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies, to assess compliance with cGMP requirements. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with cGMP requirements. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards or if previously unrecognized problems are subsequently discovered. Later discovery of previously unknown problems with a product, including adverse events or problems with manufacturing processes of unanticipated severity or frequency, or failure to comply with regulatory requirements, may also result in (1) revisions to the approved labeling to add new safety information; (2) imposition of post-market studies or clinical trials to assess new safety risks; or (3) imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things. (1) restrictions on the marketing or manufacturing of the product; (2) fines, warning letters or holds on post-approval clinical trials; (3) refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product license approvals; (4) product seizure or detention, or refusal to permit the import or export of products; or (5) injunctions or the imposition of civil or criminal penalties.

## Table of Contents

# Marketing Pharmaceutical Products Outside the United States

Outside of the United States, our ability to market our products is also contingent upon receiving marketing authorizations from regulatory authorities. The foreign regulatory approval process may include some or all of the risks associated with the FDA review and approval process set forth above, and the requirements governing the conduct of clinical trials and marketing authorization vary widely from country to country.

In the EU, marketing authorizations may be submitted through a centralized body or through a decentralized/mutual recognition or a national level process. The centralized procedure is mandatory for the approval of certain products, such as officially designated orphan medicines and medicines derived from biotechnology and high technology processes, and may be available at the applicant's option for other products that are a significant therapeutic, scientific or technical innovation or for which approval would be in the interest of public health. The centralized procedure provides for the grant of a single marketing authorization that is valid in the EEA, which consists of the EU member countries and Norway, Iceland, and Lichtenstein. The decentralized/mutual recognition procedures are available for all medicinal products that are not subject to the centralized procedure. Each EU member country has its own procedure for approval. A company may use the decentralized procedure to submit applications for marketing authorization in more than one EU country simultaneously for a product that has not previously been authorized in an EU country. In addition, the mutual recognition procedure provides for mutual recognition of national approval decisions, changes existing procedures for national approvals and establishes procedures for coordinated EU actions on products, suspensions and withdrawals. Under this procedure, the holder of a national marketing authorization for which mutual recognition is sought may submit an application to one or more EU member countries, certify that the dossier is identical to that on which the first approval was based, or explain any differences and certify that identical dossiers are being submitted to all EU member countries for which recognition is sought. Within 90 days of receiving the application and assessment report, each EU member country is required to decide whether to recognize approval. The procedure encourages member states to work with applicants and other regulatory authorities to resolve disputes concerning mutual recognition. Arbitration may be initiated when member countries fail to reach agreement. Following receipt of marketing authorization in an EU member country, the applicant is then usually (depending on the country) required to engage in pricing discussions and negotiations with a separate prescription pricing authority in that country. Commercial sales typically only commence in a country once pricing approval has been obtained.

To secure European regulatory approvals for subcutaneous Remodulin for PAH, we used the mutual recognition process. Under the rules then applicable, centralized filing was not required and we perceived the decentralized/mutual recognition procedure to be the most effective means for approval. We filed our first MAA in France in February 2001. Review of our application was completed in 2005. As a result, Remodulin was approved in 23 member countries of the EEA under the mutual recognition process described above. We withdrew applications in Spain, the United Kingdom and Ireland and are currently evaluating resubmitting applications in Spain and Ireland. In December 2011, we received approval for intravenous Remodulin in all of the 23 EEA member nations where subcutaneous Remodulin is approved.

To secure European regulatory approval for Tyvaso, we submitted an MAA to the EMA via the centralized process in 2008. Regulations in Europe have changed since we made our initial filing for Remodulin and all therapies for orphan diseases must now use the centralized process. In February 2010, we withdrew our MAA from consideration by the EMA, and do not currently intend to resubmit it as a standalone treatment for PAH due to the EMA's major objection related to findings of non-compliance with good clinical practice at two clinical sites. The EMA stated that these findings would preclude a recommendation for approval of Tyvaso in the EU. The EMA had no major objections at the time of withdrawal related to the safety or efficacy of Tyvaso.

## **Table of Contents**

# **Biologics**

Biological products used for the prevention, treatment, or cure of a disease, or condition, of a human being are subject to regulation under the FDC Act and the PHSA. Biological products are approved for marketing via a BLA that follows an application process and approval requirements that are very similar to those for NDAs. To help reduce the increased risk of the introduction of adventitious agents, the PHSA emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The PHSA also provides authority to the FDA to immediately suspend licenses in situations where there exists a danger to public health, to prepare or procure products in the event of shortages and critical public health needs, and to authorize the creation and enforcement of regulations to prevent the introduction, or spread, of communicable diseases in the United States.

After a BLA is approved, the product may also be subject to official lot release. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official lot release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA may also perform certain confirmatory tests on lots of some products, such as viral vaccines, before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products. As with drugs, after approval of biologics, manufacturers must address any safety issues that arise, are subject to recalls or a halt in manufacturing, and are subject to periodic inspection after approval.

The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (PPACA), included a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCI Act, which created an abbreviated approval pathway for biological products shown to be similar to, or interchangeable with, an FDA-licensed reference biological product. This is conceptually similar to the Hatch-Waxman Act in that it attempts to minimize duplicative testing. Biosimilarity requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency must be shown through analytical studies, animal studies, and at least one clinical study absent a waiver. In addition, only minor differences in clinically inactive components are allowable in biosimilar products. An interchangeable biological product is a biosimilar to an FDA-approved reference product that meets additional standards for interchangeability. Interchangeability requires that a product must demonstrate that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. However, intricacies associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation that are still being addressed by the FDA. In 2015, the FDA approved the first biosimilar in the United States and published a proposed rule and guidance documents relating to various provisions of the BPCI Act. For example, the FDA addressed the naming conventions and labeling of biosimilar products, including whether and how such labeling should include information from reference product labeling and identify a product's approval through the biosimilar pathway. The FDA suggested that shared non-proprietary names may not be appropriate for all biological products, noting that the naming conventions could improve pharmacovigilance, prevent inadvertent substitution among products which have not been determined to be interchangeable, avoid inaccurate perceptions of the safety and effectiveness of biological products based on their licensure pathway, and provide a consistent mechanism for healthcare professionals to

## Table of Contents

identify biological products. The FDA also released guidance recommendations relating to the clinical, scientific, and quality data required to demonstrate biosimilarity.

A reference biologic is granted twelve years of exclusivity from the time of first licensure of the reference product. The first biologic product submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product has exclusivity against other biologics submitted under the abbreviated approval pathway for the lesser of (1) one year after first commercial marketing; (2) eighteen months after approval of the initial application if there is no legal challenge; (3) eighteen months after the resolution in the applicant's favor of a lawsuit challenging the biologics' patents if an application has been submitted; or (4) 42 months after the application has been approved if a lawsuit is ongoing within the 42 month period.

Since the passage of the BPCI Act, there have been proposals to modify the exclusivity provisions. In the budget for fiscal year 2016, the Obama administration reasserted a proposal from prior years to cut the 12-year period of exclusivity down to seven years. The administration also reasserted a proposal to prohibit additional periods of exclusivity due to minor changes in product formulations. In October 2015, the United States agreed to the Trans-Pacific Partnership (TPP), an agreement with 11 other countries that addresses a variety of trade and economic issues. The TPP includes a provision that would require the signatory countries to provide a minimum of five years of exclusivity, and in some instances, eight years of exclusivity, to biological products. To come into effect, the TPP will require a requisite number of signatory countries to ratify the agreement; in the United States, such ratification, if it occurs, will be performed by Congress. It is possible that Congress could seek to harmonize the exclusivity periods in the TPP and the BPCI Act, or take other measures to modify or eliminate periods of exclusivity for biosimilar and interchangeable products.

Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries.

## Cell and Tissue Based Biologics

Manufacturers of cell and tissue based products must comply with the FDA's current good tissue practices (cGTP), which are FDA regulations that govern the methods used in, and the facilities and controls used for, the manufacture of such products. The primary intent of the cGTP requirements is to ensure that cell and tissue based products are manufactured in a manner designed to prevent the introduction, transmission and spread of communicable diseases. Cell and tissue based products may also be subject to the same approval standards, including demonstration of safety and efficacy, as other biologic and drug products, if they meet certain criteria such as if the cells or tissues are more than minimally manipulated or if they are intended for a non-homologous use (a use different from the cell's origin). In 2015, the FDA published guidance documents relating to topics such as donor screening, adverse reaction reporting, and the applicability of premarket approval and clearance requirements to cell and tissue based products. Following the numerous public comments on these draft guidance documents, the FDA scheduled a public hearing for April 2016.

## U.S. Regulation of Medical Devices

Medical devices also may be subject to FDA approval and extensive regulation under the FDC Act. Under the FDC Act, medical devices are classified into one of three classes: Class I, Class II, or Class III. The classification of a device into one of these three classes generally depends on the degree of risk associated with the medical device and the extent of control needed to ensure safety and effectiveness.

Class I devices are those for which safety and effectiveness can be assured by adherence to a set of general controls. These general controls include compliance with the applicable portions of the FDA's Quality System Regulation (QSR), which sets forth good manufacturing practice requirements; facility

## Table of Contents

registration and product listing; reporting of adverse medical events; truthful and non-misleading labeling; and promotion of the device only for its cleared or approved intended uses. Class II devices are also subject to these general controls and to any other special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. Most Class I devices require review and clearance by the FDA through the so-called 510(k) pre-market notification procedure. A Class III device requires approval of a premarket approval application (PMA), an expensive, lengthy and uncertain process that can require many years to complete. Most Class II and Class III medical devices may only be marketed in the United States if the FDA has approved a PMA application for the device or cleared the device in response to a 510(k) submission. There is also an alternative pathway to approval for low or moderate risk devices that are not classified and for which no predicate device exists, known as de novo classification.

When 510(k) clearance is sought, a sponsor must submit a pre-market notification demonstrating that the proposed device is substantially equivalent to a previously marketed device, also referred to as a "predicate" device. If the FDA agrees that the proposed device is substantially equivalent to the predicate device, then 510(k) clearance to market will be granted. After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require pre-market approval. In recent years, the FDA has issued guidance recommendations relating to aspects of the FDA's 510(k) review process, including the use of multiple predicates and the content of 510(k) summaries, and the criteria the FDA uses to determine whether a 510(k) satisfies the minimum threshold of acceptability to be accepted for substantive review.

Clinical trials are almost always required to support a PMA and are sometimes required for a 510(k) pre-market notification. These trials generally require FDA approval by submitting an application for an investigational device exemption, or IDE application. An IDE application must be supported by preclinical data, such as animal and laboratory testing results, which show that the device is safe to test in humans and that the study protocols are scientifically sound. Studies of devices that pose a significant risk require approval from both the FDA and an Institutional Review Board (IRB) prior to initiation of the study. A "nonsignificant" risk device study does not require submission of an IDE application to the FDA but does require IRB approval prior to initiation of the study. Nonsignificant risk device studies must comply with abbreviated IDE requirements.

Both before and after a medical device is commercially distributed, manufacturers and marketers of the device have ongoing responsibilities under FDA regulations. The FDA reviews design and manufacturing practices, labeling and record keeping, and manufacturers' required reports of adverse experiences and other information to identify potential problems with marketed medical devices. Device manufacturers are subject to periodic and unannounced inspection by the FDA for compliance with the QSR, current good manufacturing practice requirements that govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, servicing, labeling, storage, installation, and distribution of all finished medical devices intended for human use.

If the FDA finds that a manufacturer has failed to comply or that a medical device is ineffective or poses an unreasonable health risk, it can institute or seek a wide variety of enforcement actions and remedies, ranging from a public warning letter to more severe actions such as:

32

fines, injunctions, and civil penalties;
recall or seizure of products;
operating restrictions, partial suspension or total shutdown of production;
refusing requests for 510(k) clearance or PMA approval of new products;
withdrawing 510(k) clearances or PMA approvals already granted; and

## **Table of Contents**

criminal prosecution.

The FDA also has the authority to require repair, replacement or refund of the cost of a medical device under certain circumstances.

The FDA also administers certain controls over the import and export of medical devices to and from the United States. Additionally, each foreign country subjects such medical devices to its own regulatory requirements. In the EU, a single regulatory approval process has been created, and approval is represented by the CE Mark.

A combination product is a product composed of a combination of a drug, device, or biological product. Each combination product is assigned to a specific FDA center based on which constituent part of the combination product provides the primary mode of action. In 2015, the FDA released draft guidance recommendations relating to the application of cGMP requirements to combination products. The nebulizer used with our Tyvaso Inhalation System was included in our NDA for Tyvaso as a drug-device combination product, and was cleared by the FDA subject to compliance with the QSR as it applies to combination products. In 2012, we received FDA approval for a modified Tyvaso Inhalation System using an updated nebulizer (TD-100) based on the results of the completion of the QSR compliance commitments.

# Government Reimbursement of Pharmaceutical Products

In the United States, many independent third-party health plans, and government health care programs, pay for patient use of our commercial products. Medicare is the federal program that provides health care benefits to senior citizens and certain disabled and chronically ill persons. Medicaid is the federal program jointly funded and administered by the states to provide health care benefits to certain indigent persons. Unituxin is administered entirely as an in-patient therapy and would typically be reimbursed under Medicare Part A. However, because Unituxin is indicated for treatment of a pediatric cancer, Medicare beneficiaries are unlikely to receive this treatment. The purchase prices for Remodulin and Tyvaso are reimbursed within the Medicare Part B program. The Medicare Part B contractors who administer the program provide reimbursement for Remodulin and Tyvaso according to statutory guidelines. In return for the inclusion of our commercial products Adcirca and Orenitram in the Medicare Part D program, we have agreed to pay rebates to Medicare Part D plan sponsors that reimburse these products. The state Medicaid programs also reimburse the cost of our commercial products at reimbursement rates established by statutory guidelines. Because Remodulin, Tyvaso, Adcirca, Orenitram and Unituxin are covered and reimbursed by state Medicaid programs, we are mandated to pay a rebate to those state Medicaid programs. We are required by government contract to sell our commercial products under contracts with the Department of Veterans Affairs, Department of Defense, Public Health Service and numerous other federal agencies as well as certain hospitals that are designated as 340B covered entities (entities designated by federal programs to receive drugs at discounted prices) at prices that are significantly below the price we charge to our specialty distributors. These programs and contracts are highly regulated and impose restrictions on our business. Failure to comply with these regulations and restrictions could result in a loss of our ability to continue receiving reimbursement for our drugs, exclusion of our products from reimbursement under the federal healthcare programs, or debarment, and expose us to liability under federal and state false claims laws. We estimate that between 35-50% of Remodulin, Tyvaso, Adcirca and Orenitram sales are reimbursed under the Medicare and Medicaid programs.

#### Anti-Kickback, False Claims Laws and The Prescription Drug Marketing Act

In addition to FDA restrictions on marketing pharmaceutical, biological and medical device products, several other types of state and federal laws have been applied to restrict certain marketing practices in the pharmaceutical and medical device industries in recent years. These laws include

## Table of Contents

anti-kickback statutes and false claims statutes. The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of, or referring an individual for the furnishing of, any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Violations of the anti-kickback statute are punishable by imprisonment, criminal fines, civil monetary penalties and exclusion from participation in federal healthcare programs. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor.

The federal False Claims Act prohibits any person from, among other things, knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement material to a false claim. Many pharmaceutical and other healthcare companies have been prosecuted under the False Claims Act for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, companies have been prosecuted under the False Claims Act on the basis of allegations relating to marketing practices, including off-label promotion. The majority of states also have statutes or regulations similar to the federal anti-kickback statute and False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. Sanctions under these federal and state laws may include civil penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines, and imprisonment.

As part of the sales and marketing process, pharmaceutical companies frequently provide samples of approved drugs to physicians. The Prescription Drug Marketing Act (PDMA) imposes requirements and limitations upon the distribution of drugs and drug samples, and prohibits states from licensing distributors of prescription drugs unless the state licensing program meets certain federal guidelines that include minimum standards for storage and handling, as well as record keeping requirements for information regarding sample requests and distribution. The PDMA sets forth civil and criminal penalties for violations. In addition, PDMA requires manufacturers and distributors to submit similar drug sample information to FDA.

## Patient Protection and Affordable Care Act of 2010

PPACA is intended to expand healthcare coverage within the United States. Several provisions of the law, which have varying effective dates, have impacted us and have increased certain of our costs. PPACA imposes an annual fee on pharmaceutical manufacturers, based on the manufacturer's sale of branded pharmaceuticals and biologics (excluding orphan drugs) to certain U.S. government programs during the preceding year; expands the 340B drug discount program (excluding orphan drugs) including the creation of new penalties for non-compliance; and includes a 50% discount on brand name drugs for Medicare Part D participants in the coverage gap, or "donut hole." Effective beginning in 2010, the law also revised the definition of "average manufacturer price" for reporting purposes, which could increase the amount of the Medicaid drug rebates paid to states.

As noted above under *Governmental Regulation Biologics*, the PPACA also created a regulatory pathway for the abbreviated approval of biological products that are demonstrated to be "biosimilar" or "interchangeable" with an FDA-approved biological product. In addition, PPACA imposes new annual reporting requirements for pharmaceutical, biological and device manufacturers with regard to

## Table of Contents

payments or other transfers of value made to physicians and teaching hospitals. In addition, pharmaceutical, biological and device manufacturers are required to report annually investment interests held by physicians and their immediate family members during the preceding calendar year. Such information was required to be made publicly available by the Secretary of Health and Human Services in a searchable format beginning on September 30, 2014. Failure to submit required information may result in civil monetary penalties of up to \$150,000 per year (and up to \$1 million per year for "knowing failures") for all payments, transfers of value or ownership or investment interests not reported in an annual submission. Further, the PPACA amends the intent requirement of the federal anti-kickback and criminal health care fraud statute. A person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them. In addition, the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

# State Pharmaceutical and Medical Device Marketing Laws

If not preempted by the PPACA, several jurisdictions, including the District of Columbia, Maine, Massachusetts, Minnesota, Vermont and West Virginia, require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and to report gifts and payments to healthcare practitioners in those jurisdictions. Some of these jurisdictions also prohibit various marketing related activities. Still other states require the posting of information relating to clinical studies and their outcomes. In addition, certain states, such as California, Connecticut, Nevada, and Massachusetts, require pharmaceutical companies to implement compliance programs or marketing codes and several other states are considering similar proposals. Compliance with these laws is difficult and time consuming, and companies that do not comply with these state laws face civil penalties or other civil enforcement action.

#### **Employees**

We had approximately 750 employees as of February 7, 2016. The success of our business is highly dependent on attracting and retaining highly talented and qualified personnel.

#### **Industry Segments and Geographic Areas**

Since March 2011, our core business has been pharmaceuticals, in which we closely monitor the revenues and gross margins generated by our commercial products. We sell our products in the United States and throughout the rest of the world. The information required by Item 101(b) and 101(d) of Regulation S-K relating to financial information about industry segments and geographical areas, respectively, is contained in Note 17 Segment Information to our consolidated financial statements included in this Annual Report on Form 10-K.

# **Corporate Website**

Our Internet website address is <a href="http://www.unither.com">http://www.unither.com</a>. Our filings on Form 10-K, Form 10-Q, Form 3, Form 4, Form 5, Form 8-K and any and all amendments thereto are available free of charge through this internet website as soon as reasonably practicable after they are filed with or furnished to the Securities and Exchange Commission (SEC). They are also available through the SEC at <a href="http://www.sec.gov/edgar/searchedgar/companysearch.html">http://www.sec.gov/edgar/searchedgar/companysearch.html</a>.

## Table of Contents

## EXECUTIVE OFFICERS OF THE REGISTRANT

The following is a list, as of February 17, 2016, setting forth certain information regarding our executive officers. Each executive officer holds office until the first meeting of the Board of Directors after the annual meeting of shareholders, and until his or her successor is elected and qualified or until his or her earlier resignation or removal. Each executive officer's employment will end pursuant to the terms of his or her employment contract.

Name	Age	Position
Martine A. Rothblatt, Ph.D., J.D., M.B.A.	61	Chairman, Co-Chief Executive Officer and Director
Roger Jeffs, Ph.D.	54	President, Co-Chief Executive Officer and Director
David Zaccardelli, Pharm.D.	51	Executive Vice President and Chief Operating Officer
James C. Edgemond	48	Chief Financial Officer and Treasurer
		Executive Vice President, General Counsel and Corporate
Paul A. Mahon, J.D.	52	Secretary

Martine A. Rothblatt, Ph.D., J.D., M.B.A., founded United Therapeutics in 1996 and has served as Chairman and Chief Executive Officer since its inception. In January 2015, she became United Therapeutics' Co-Chief Executive Officer upon the promotion of Roger Jeffs to Co-Chief Executive Officer. Prior to United Therapeutics, she founded and served as Chairman and Chief Executive Officer of SiriusXM Satellite Radio. She is a co-inventor on four of our patents pertaining to treprostinil.

Roger Jeffs, Ph.D., received his undergraduate degree in chemistry from Duke University and his Ph.D. in pharmacology from the University of North Carolina. Dr. Jeffs joined United Therapeutics in September 1998 as Director of Research, Development and Medical. He was promoted to Vice President of Research, Development and Medical in 2000 and to President and Chief Operating Officer in 2001. In January 2015, Dr. Jeffs was promoted to Co-Chief Executive Officer. From 1993 to 1995, Dr. Jeffs worked at Burroughs Wellcome & Company where he was a member of the clinical research team that developed Flolan, the first FDA-approved therapy for patients with PAH. From 1995 to 1998, Dr. Jeffs worked at Amgen, Inc. where he served as the worldwide clinical leader of the Infectious Disease Program. Dr. Jeffs currently leads our global clinical, commercial, manufacturing, regulatory, medical affairs, pharmacovigilance and business development efforts.

David Zaccardelli, Pharm.D., received his doctor of pharmacy from the University of Michigan. Dr. Zaccardelli joined United Therapeutics in 2004 as Vice President, Pharmaceutical Development. He was promoted to Senior Vice President, Pharmaceutical Development in 2006, to Executive Vice President, Pharmaceutical Development & Operations in April 2008 and to Chief Manufacturing Officer and Executive Vice President, Pharmaceutical Development in November 2008. In January 2015, Dr. Zaccardelli was promoted to Executive Vice President and Chief Operating Officer. From 1988 to 1996, Dr. Zaccardelli worked at Burroughs Wellcome & Company and Glaxo Wellcome, Inc. in a variety of clinical research positions. He also served as Director of Clinical and Scientific Affairs for Bausch & Lomb Pharmaceuticals, Inc. from 1996 to 1997. Dr. Zaccardelli founded and led a startup company focused on contract pharmaceutical development services from 1997 through 2003.

James C. Edgemond joined United Therapeutics in January 2013 as Treasurer and Vice President, Strategic Financial Planning.

Mr. Edgemond was promoted to Chief Financial Officer and Treasurer in March 2015. Prior to joining United Therapeutics, he was Vice President, Corporate Controller and Treasurer of Clark Construction Group from November 2008 through January 2013. He also served in a variety of roles at The Corporate Executive Board Company from 1998 to 2008, including most recently as Executive Director, Finance from 2005 to 2008. He began his career as a public accountant

## **Table of Contents**

at KPMG Peat Marwick LLP, where he served in a variety of roles from 1990 through 1998, including most recently as a Senior Manager.

Paul A. Mahon, J.D., has served as General Counsel and Corporate Secretary of United Therapeutics since its inception in 1996. In June 2001, Mr. Mahon joined United Therapeutics full-time as Senior Vice President, General Counsel and Corporate Secretary. In November 2003, Mr. Mahon was promoted to Executive Vice President, General Counsel and Corporate Secretary. Prior to June 2001, he served United Therapeutics, beginning with its formation in 1996, in his capacity as principal and managing partner of a law firm specializing in technology and media law.

# ITEM 1A. RISK FACTORS

## **Forward-Looking Statements**

This Annual Report on Form 10-K contains forward-looking statements made pursuant to the safe harbor provisions of Section 21E of the Securities Exchange Act of 1934 (the Exchange Act) and the Private Securities Litigation Reform Act of 1995. These statements, which are based on our beliefs and expectations as to future outcomes, include, among others, statements relating to the following:

Expectations of revenues, expenses, profitability, and cash flows, including our expectation that Orenitram® (treprostinil) Extended Release Tablets (Orenitram) cost of product sales as a percentage of its net product sales will become comparable to our other treprostinil-based commercial products;

The sufficiency of current and future working capital to support operations;

Our ability to obtain financing on terms favorable to us or at all;

The value of our common stock and our ability and plans repurchase common stock under our \$500 million share repurchase program, which commenced in January 2016;

The maintenance of domestic and international regulatory approvals;

Our ability to maintain attractive pricing for our products, in light of increasing competition and pressure from government and other payers to decrease the costs associated with healthcare;

The expected volume and timing of sales of our existing commercial products Remodulin® (treprostinil) Injection (Remodulin), Tyvaso® (treprostinil) Inhalation Solution (Tyvaso), Orenitram, Adcirca® (tadalafil) Tablets (Adcirca) and Unituxin® (dinutuximab) Injection (Unituxin) and potential future commercial products such as esuberaprost;

The timing and outcome of clinical studies, other research and development efforts, and related regulatory filings and approvals, including: (1) our plans to complete our FREEDOM-EV study of Orenitram and our BEAT study of esuberaprost and Tyvaso, and achieve a time to clinical worsening endpoint in each of these studies; (2) our aim to obtain approval from the U.S. Food and Drug Administration (FDA) for Orenitram as a combination therapy following our FREEDOM-EV study; (3) our plan to file for approval of Orenitram in Europe upon the successful completion of the FREEDOM-EV study; (4) our phase III clinical trial of esuberaprost in combination with Tyvaso; (5) our collaboration with DEKA Research & Development Corp. (DEKA) to develop a pre-filled, semi-disposable pump system for subcutaneous Remodulin; and (6) pending regulatory filings by Medtronic, Inc. (Medtronic) and us with respect to the Remodulin Implantable System, as well as the consent decree relating to Medtronic's implantable pump;

The outcome of potential future regulatory actions, including audits and inspections, by the FDA and international regulatory agencies;

## **Table of Contents**

The impact of competing therapies on sales of our commercial products, including (1) the impact of generic products such as (a) generic sildenafil, which launched in 2012; (b) generic tadalafil, which may become available following patent expiry in November 2017; and (c) generic forms of subcutaneous and intravenous treprostinil, which we expect two generic companies will launch in June 2018 and December 2018; and (2) newly-developed therapies, such as Uptravi® (selexipag);

The expectation that we will be able to produce sufficient quantities and maintain adequate inventories of our commercial products, through both our in-house production capabilities and third-party production sites, and our ability to obtain and maintain related approvals by the FDA and other regulatory agencies;

The adequacy of our intellectual property protections and the validity and expiration dates of the patents we own or license;

Our expectations regarding our ability to defend our intellectual property relating to Remodulin, Tyvaso and Orenitram against generic and other challenges, including but not limited to our ongoing litigation with Watson Laboratories, Inc. (Watson) related to Tyvaso, an Abbreviated New Drug Application (ANDA) filed by Actavis Laboratories FL, Inc. (Actavis) seeking approval to market a generic version of Orenitram, and the petition by SteadyMed Ltd. (SteadyMed) seeking to invalidate one of our patents covering treprostinil, which is the active ingredient in Remodulin, Tyvaso and Orenitram;

Any statements that include the words "believe," "seek," "expect," "anticipate," "forecast," "project," "intend," "estimate," "should," "could," "may," "will," "plan," or similar expressions;

Other statements contained or incorporated by reference in this Annual Report on Form 10-K that are not historical facts; and

The statements identified as forward-looking statements may appear in *Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations* or elsewhere in this Annual Report on Form 10-K.

These statements are subject to risks and uncertainties and our actual results may differ materially from anticipated results. Factors that may cause such differences include, but are not limited to, those discussed below. We undertake no obligation to publicly update forward-looking statements, whether as a result of new information, future events or otherwise.

#### **Risks Related to Our Business**

We rely heavily on sales of Remodulin, Tyvaso, Orenitram and Adcirca to generate revenues and support our operations.

Sales of our current PAH therapies (Remodulin, Tyvaso, Orenitram and Adcirca) comprise substantially all of our revenues. A wide variety of events, many of which are described in other risk factors below, could cause sales of these products to decline, or to grow more slowly than expected. For instance, we would be unable to sell any of these products if their regulatory approvals were withdrawn. Any substantial change in the prescribing practices or dosing patterns of patients using Remodulin, Tyvaso, Orenitram or Adcirca due to combination or competing therapies, side effects, adverse events, deaths or any other reasons could decrease related revenues. We also face potential generic competition. For example, during the fourth quarter of 2012, generic sildenafil became commercially available, which could negatively affect future demand for Adcirca. We could also face generic competition for Adcirca following patent expiry in November 2017. We also settled our patent litigation with Sandoz and Teva relating to Remodulin, and have agreed that Sandoz and Teva will be permitted to launch their generic versions of Remodulin in the United States in June 2018 and December 2018,

## **Table of Contents**

respectively, although they may be permitted to launch earlier under certain circumstances. We are also defending our intellectual property related to Tyvaso and Orenitram against generic challenges by two additional generic companies, and another company has filed a petition challenging the validity of one of our patents relating to Remodulin, Tyvaso and Orenitram. In addition, we rely on third parties to produce, market, distribute and sell all of our commercial products. The inability of any one of these third parties to perform these functions satisfactorily could result in a reduction in sales. In addition, any failure to effectively manage our internal production processes could result in an inability to meet patient demand. Because we are highly dependent on sales of Remodulin, Tyvaso, Adcirca and Orenitram, a reduction in sales of any one of these products could have a material adverse impact on our operations.

If our products fail in clinical trials, we will be unable to obtain or maintain FDA and international regulatory approvals and will be unable to sell those products.

To obtain regulatory approvals from the FDA and international regulatory agencies such as the European Medicines Agency (EMA), we must conduct clinical trials demonstrating that our products are safe and effective. In the past, several of our product candidates failed or were discontinued at various stages in the development process. Moreover, we may need to amend ongoing trials or the FDA and/or international regulatory agencies may require us to perform additional trials beyond those we planned. Such occurrences could result in significant delays and additional costs, and related clinical trials may be unsuccessful. Approval of a New Drug Application (NDA) or Biologics License Application (BLA) could be subject to delays if the FDA determines that it cannot review or approve the application as submitted. In such a case, the FDA would issue a refuse-to-file letter or a complete response letter outlining deficiencies in the submission, and the FDA may require substantial additional studies, testing or information in order to complete its review of the application. We may fail to address any of these deficiencies adequately and consequently would be unable to obtain FDA approval to market the product candidate.

In addition, we are enrolling a phase IV clinical trial called FREEDOM-EV, which is a study of Orenitram in combination with other approved therapies for pulmonary arterial hypertension (PAH). One primary endpoint of the study is time to clinical worsening. The primary endpoint of our phase III study of esuberaprost in combination with Tyvaso is also time to clinical worsening. We have not previously conducted a study with time to clinical worsening as its primary endpoint. Our inexperience with this type of trial design may impact our ability to conduct these trials appropriately and achieve positive results, or complete the trials within our anticipated timetable. In particular, failure to prove the efficacy of Orenitram in combination with other PAH therapies could materially limit the commercial potential of Orenitram and impede our growth.

The length of time that it takes for us to complete clinical trials and obtain regulatory approval for marketing varies by product, product use and country. Furthermore, we cannot predict with certainty the length of time it will take to complete necessary clinical trials or obtain regulatory approval of our future products.

Our clinical trials may be discontinued, delayed or disqualified for various reasons. These reasons include:

The drug is ineffective, or physicians and/or patients believe that the drug is ineffective;

We fail to reach agreement with the FDA or non-U.S. regulatory agencies regarding the scope or design of our clinical trials;

Patients do not enroll in our studies at the rate we expect;

We are unable to obtain approval from institutional review boards to conduct clinical trials at their respective sites;

## Table of Contents

Ongoing or new clinical trials conducted by drug companies in addition to our own clinical trials reduce the availability of patients for our trials;

Other investigational or approved therapies are viewed as more effective or convenient by physicians or patients;

Our clinical trial sites, contracted clinical trial administrators or clinical studies conducted entirely by third parties do not adhere to trial protocols and required quality controls under FDA good clinical practice (GCP) regulations and similar regulations outside the United States;

Patients experience severe side effects during treatment or die during our trials because of adverse events related to the trial drug, advanced disease, or other medical complications; and

The results of our clinical trials conducted in countries outside of the United States are not acceptable to the United States or other countries, and the results of our clinical trials conducted in the United States are not acceptable to regulators in other countries.

In addition, the FDA and its international counterparts have substantial discretion over the approval process for pharmaceutical products. As such, these regulatory agencies may not agree that we have demonstrated the requisite level of product safety and efficacy to grant approval.

## We may not compete successfully with established and newly developed drugs or products, or the companies that develop and market them.

We compete with well-established drug companies for, among other things, funding, licenses, expertise, personnel, clinical trial patients and investigators, consultants and third-party collaborators. We also compete with these companies for market share. Most of these competitors have substantially greater financial, marketing, manufacturing, sales, distribution and technical resources, and a larger number of approved products, than we do. These competitors also possess greater experience in areas critical to success such as research and development, clinical trials, sales and marketing and regulatory matters. There are numerous treatments that compete with our commercial therapies, as well as several other therapies under development. For the treatment of PAH, we compete with a number of approved products in the United States and worldwide, including the following: Adempas®, Flolan®, Ilomedin®, Letairis®, Opsumit®, Revatio®, Tracleer®, Uptravi®, Veletri®, Volibris®, Ventavis®, generic epoprostenol and generic sildenafil citrate. Patients and doctors may perceive these competing products, or products developed in the future, as safer, more effective, more convenient and/or less expensive than our therapies. Alternatively, doctors may reduce the prescribed doses of our products if they prescribe them in combination with our competitors' products. In addition, many competing PAH therapies are less invasive than Remodulin and the use of these products may delay or prevent initiation of Remodulin therapy. Any of these circumstances could negatively impact our operating results.

# Development of new products or technologies by others may make our products obsolete or seemingly inferior.

Other companies may introduce new products that may render all or some of our technologies and products obsolete or noncompetitive. For example, Uptravi was recently approved by the FDA for the treatment of PAH, and will compete directly with Orenitram. Our commercial therapies may also have to compete with investigational products currently in development, such as Trevyent , which is a single-use, pre-filled pump being developed by SteadyMed to deliver a two-day supply of treprostinil subcutaneously using its PatchPump® technology. In January 2016, SteadyMed announced that Trevyent has been granted orphan drug designation by the FDA for the treatment of PAH. In addition, alternative approaches to treating chronic diseases, such as gene therapy, cell therapy or transplantation technologies, may make our products obsolete or noncompetitive. If introduced into the market, investigational therapies for PAH could be used in combination with, or as a substitute for, our therapies. If this occurs, doctors may reduce or discontinue the use of our products for their patients.

## Table of Contents

Sales of our products are subject to reimbursement from government agencies and other third parties. Pharmaceutical pricing and reimbursement pressures may negatively impact our sales.

The commercial success of our products depends, in part, on the availability of reimbursements by governmental payers such as Medicare and Medicaid, and private insurance companies. An estimated 35-50% of Remodulin, Tyvaso, Adcirca and Orenitram sales in the United States are reimbursed under the Medicare and Medicaid programs. In the United States, the European Union and other potentially significant markets for our products such as China and Japan, government payers and/or third-party payers are increasingly attempting to limit or regulate the price of medicinal products and frequently challenge the pricing of new and expensive drugs. Our prostacyclin analogue products (Remodulin, Tyvaso and Orenitram) and our oncology product (Unituxin) are expensive therapies. Consequently, it may be difficult for our distributors to obtain adequate reimbursement for our products from third-party payers to motivate such distributors to support our products. Alternatively, third-party payers may reduce the amount of reimbursement for our products based on changes in pricing of other therapies for the same disease. If third-party payers do not approve our products for reimbursement, or limit reimbursements, patients and physicians could choose competing products that are approved for reimbursement or provide lower out-of-pocket costs.

In the United States, the federal government and others are increasingly focused on analyzing the impact of various regulatory programs on the federal deficit, which could result in increased pressure on federal programs to reduce costs. In addition, financial pressures may cause the federal government or other third-party payers to seek cost containment more aggressively through mandatory discounts or rebates on our products, policies requiring the automatic substitution of generic products, more rigorous requirements for initial reimbursement approvals for new products or other similar measures. For example, there have been proposals to reduce reimbursement rates and/or adopt mandatory rebates under Medicare Part B, which covers Remodulin and Tyvaso. A reduction in the availability or extent of reimbursement from government health care programs could have a material adverse effect on our business and results of our operations.

In Europe, the success of our commercial products and future products depends largely on obtaining and maintaining government reimbursement at acceptable levels. In many European countries, patients are unlikely to use prescription drugs that are not reimbursed by their governments. Countries in Europe are under increasing pressure to reduce the cost of health care. Changes to current reimbursement policies may adversely affect our ability to sell our products or sell our products on a profitable basis. In many markets outside the United States, governments control the prices of prescription pharmaceuticals through the implementation of reference pricing, price cuts, rebates, revenue-related taxes and profit control. Furthermore, international governments expect prices of prescription pharmaceuticals to decline over the life of the product or as prescription volumes increase. In addition, in December 2011, we received marketing approval for the intravenous use of Remodulin in most of the countries that are members of the European Economic Area (EEA); however, we are in the process of obtaining approval of our risk management plan on a country-by-country basis, and must obtain pricing approval in each of these member countries before we can market Remodulin. Similarly, we received European Commission approval for Unituxin during the third quarter of 2015, and must obtain pricing and reimbursement approvals on a country-by-country basis before launching in individual countries in Europe. Delays in obtaining these approvals, or failure to obtain satisfactory pricing approvals, could impact our future sales growth. Additionally, in granting pricing approval for the intravenous use of Remodulin, a member country may approve a lower reimbursement price for intravenous Remodulin than for subcutaneous Remodulin, or reduce the reimbursement price for both methods of administering Remodulin. Any regulatory action reducing the reimbursement rates for intravenous and subcutaneous Remodulin could have a material adverse effect on our revenues, results of operations and our business.

## **Table of Contents**

# Our production strategy exposes us to significant risks.

We must be able to produce sufficient quantities of our commercial products to satisfy the growing demand for our products. We produce Remodulin, Orenitram, Tyvaso and Unituxin, including the active ingredient in each of these products, at our own facilities and rely on third parties for additional production capacity. We rely on Minnetronix, Inc. as the sole manufacturer of the Tyvaso Inhalation System, and on Eli Lilly and Company (Lilly) as the sole manufacturer of Adcirca. In addition, if the Remodulin Implantable System is approved, we will be reliant on Medtronic as the sole manufacturer of the Synchromed II infusion system.

We substantially rely on third parties to adhere to and maintain production processes in accordance with all applicable regulatory requirements. If any of these critical third-party production and supply arrangements are interrupted for compliance issues or other reasons, we may not have sufficient inventory to meet future demand. In addition, any change in suppliers and/or service providers could interrupt the production of our commercial products and impede the progress of our commercial launch plans and clinical trials.

In addition, our internal production process also subjects us to risks as we engage in increasingly complex production processes. For example, Remodulin, Tyvaso and Unituxin must be formulated in a sterile environment, which is challenging to maintain on a commercial scale. In addition, Unituxin is a monoclonal antibody. As with all biologic products, monoclonal antibodies are inherently more difficult to produce than our treprostinil-based products and involve increased risk of viral and other contaminants. Finally, we have limited experience producing Orenitram and Unituxin on a commercial scale, and currently all Orenitram and Unituxin production is performed internally. It could take substantial time to establish an FDA-approved contract manufacturer as a back-up supplier of our newest products, Orenitram and Unituxin, or this process may not be successful at all.

Additional risks we face with our production strategy include the following:

We and our third-party producers are subject to the FDA's current Good Manufacturing Practices, current Good Tissue Practices and similar international regulatory standards. We are limited in our ability to exercise control over regulatory compliance by our third-party producers;

As we expand our production operations to include new elements of the production process or new products, we may experience difficulty designing and implementing processes and procedures to ensure compliance with applicable regulations;

Even if we and our third-party producers are in compliance with applicable domestic and international drug production regulations, the sterility and quality of the products being produced could be substandard and, therefore, such products would be unavailable for sale or use or subject to recalls;

If we had to replace our own production operations or a third-party producer, the FDA and its international counterparts would require new testing and compliance inspections. Furthermore, a new producer would have to be familiarized with the processes necessary to produce and commercially validate our products, as producing our treprostinil-based and biologic products is complex:

We may be unable to contract with needed producers on satisfactory terms or at all; and

The supply of materials and components necessary to produce and package our products may become scarce or unavailable. Disruptions to the supply of these materials could delay the production and subsequent sale of such products. Any products produced with substituted materials or components would be subject to approval from the FDA and international regulatory agencies before they could be sold. The timing of any such regulatory approval is difficult to predict.

## Table of Contents

Any of these factors could disrupt sales of our commercial products, delay clinical trials or commercialization of new products, result in product liability claims and product recalls, and entail higher costs. Interruptions in our production process could be significant given the length of time and complexity involved in obtaining necessary regulatory approvals for alternative arrangements, through either third parties or internal manufacturing processes.

We rely in part on third parties to perform activities that are critical to our business. Our ability to generate commercial sales or conduct clinical trials could suffer if our third-party suppliers and service providers fail to perform.

Third parties assist us in: (1) producing our commercial products; (2) conducting clinical trials, preclinical studies and other research and development activities; (3) obtaining regulatory approvals; (4) conducting pharmacovigilance-related and product complaint activities, including drug safety, reporting adverse events and product complaints; and (5) marketing and distributing our products. In addition, we rely on independent third party manufacturers for the availability of pumps and ancillary supplies necessary for the delivery of subcutaneous and intravenous Remodulin, and in most cases we have no contracts with these manufacturers. The involvement of third parties is necessary because we do not possess the internal capacity, and in certain cases the expertise, to perform all of these functions. Accordingly, the success of these third parties in performing their contractual obligations is critical to our operations.

For risks relating to the involvement of third parties in our production process, see the risk factor above, entitled *Our production strategy* exposes us to significant risks.

We rely on Accredo Health Group, Inc. and CVS Caremark to distribute and sell Remodulin, Tyvaso and Orenitram in the United States. These distributors are also partially responsible for negotiating reimbursements from third-party payers for the cost of our therapies. We also rely on ASD Specialty Healthcare, Inc. to distribute and sell Unituxin in the United States. We also rely on various distributors to market, distribute and sell Remodulin and Unituxin outside the United States. From time-to-time, we increase the price of products sold to our U.S.-based and international distributors. Our price increases may not be fully reimbursed by third-party payers. If our distributors do not achieve acceptable profit margins on our products, they may reduce or discontinue the sale of our products. Furthermore, if our distributors devote fewer resources to sell our products or are unsuccessful in their sales efforts, our revenues may decline materially. Outside the United States, we are substantially reliant on our international distributors to maintain regulatory approvals for our products and to market and sell our products in compliance with applicable laws and regulations.

We rely on Lilly to manufacture and supply Adcirca for us, and we use Lilly's pharmaceutical wholesaler network to distribute Adcirca. If Lilly is unable to manufacture or supply Adcirca or its distribution network is disrupted, it could delay, disrupt or prevent us from selling Adcirca. In addition, Lilly has the right to determine the price of Adcirca, which generally moves in parity with the price Lilly sets for Cialis® (both of these products contain the same active ingredient). Changes in Lilly's prices could adversely impact demand or reimbursement for Adcirca, particularly in light of the commercial availability of generic sildenafil, the active ingredient in Revatio, which could be prescribed in lieu of Adcirca.

In addition, any change in service providers could interrupt the distribution of our commercial products and our other products and services, and impede the progress of our clinical trials, commercial launch plans and related revenues.

We rely heavily on third-party contract research organizations, contract laboratories, clinical investigative sites and other third-parties to conduct our clinical trials, preclinical studies and other research and development activities. In addition, the success of certain products we are developing will depend on clinical trials sponsored by third parties. Failure by any third party to conduct or assist us in

## Table of Contents

conducting clinical trials in accordance with study protocols, quality controls and GCP, or other applicable U.S. or international requirements or to submit associated regulatory filings, could limit or prevent our ability to rely on results of those trials in seeking regulatory approvals.

We rely heavily on Medtronic for the success of our program to develop an implantable pump to deliver intravenous Remodulin (the Remodulin Implantable System). Medtronic has completed a clinical study in this regard, and submitted a Premarket Approval Application (PMA) seeking FDA approval for the Remodulin Implantable System. We rely on Medtronic to respond to FDA requests for additional information with respect to its PMA, and following approval we will rely on Medtronic to manufacture the Remodulin Implantable System and to maintain appropriate quality controls relating to the system. We also note that Medtronic has received a consent decree requiring the company to stop manufacturing, designing and distributing SynchroMed II implantable infusion pump systems, except in limited circumstances, citing violations of the quality system regulation for medical devices. The consent decree will remain in effect until the FDA has determined that Medtronic has met all the provisions listed in the consent decree. It is unclear how this consent decree will impact our program to develop and commercialize the Remodulin Implantable System, and we anticipate further clarity in 2016 when we anticipate FDA will respond to Medtronic's PMA filing. As such, we can provide no assurances as to the timing or likelihood of the Remodulin implantable pump program's success. Similarly, we rely heavily on DEKA for the development of a pre-filled, semi-disposable pump system for subcutaneous Remodulin.

We are reliant on third parties to supply pumps and other supplies necessary to deliver Remodulin. There are a limited number of pumps available in the market, and the discontinuation of any particular pump could have a material, adverse impact on our Remodulin revenues if a viable supply of an alternate pump is not available.

Our operations must comply with extensive laws and regulations in the United States and other countries, including FDA regulations. Failure to obtain approvals on a timely basis or to achieve continued compliance could delay, disrupt or prevent the commercialization of our products.

The products we develop must be approved for marketing and sale by regulatory agencies and, once approved, are subject to extensive regulation. Our research and development efforts must comply with extensive regulations, including those promulgated by the FDA and the United States Department of Agriculture. The process of obtaining and maintaining regulatory approvals for new drugs is lengthy, expensive and uncertain. The regulatory approval process is particularly uncertain for our lung transplantation programs, which include the development of xenotransplantation, regenerative medicine and cell-based products. The manufacture, distribution, advertising and marketing of our products are also subject to extensive regulation, including strict pharmacovigilance and adverse event and medical device reporting requirements. Any future product approvals we receive could be accompanied by significant restrictions on the use or marketing of a given product. Furthermore, our product candidates may fail to receive marketing approval on a timely basis, or at all. If granted, product approvals can be withdrawn for failure to comply with regulatory requirements, such as post-marketing requirements and post-marketing commitments, or upon the occurrence of adverse events subsequent to commercial introduction.

Discovery of previously unknown problems with our marketed products or problems with our manufacturing, regulatory, compliance, research and development, pharmacovigilance and adverse event reporting, marketing or sales activities could result in regulatory restrictions on our products up to and including withdrawal of our products from the market. If we fail to comply with applicable regulatory requirements, we could be subject to penalties that may consist of fines, suspension of regulatory approvals, product recalls, seizure of our products and/or criminal prosecution. In addition, our reputation could be harmed as a result of any such regulatory restrictions or actions, and patients and

## Table of Contents

physicians may avoid the use of our products even after we have resolved the issues that led to such regulatory action.

## We are subject to ongoing regulatory review of our currently marketed products.

After our products receive regulatory approval, they remain subject to ongoing regulatory requirements, which can impact, among other things, product labeling, manufacturing practices, pharmacovigilance and adverse event and medical device reporting, complaint processing, storage, distribution, advertising and promotion, and record keeping. If we do not comply with applicable regulations, the range of possible sanctions may include: (1) adverse publicity; (2) product recalls or seizures; (3) fines; (4) total or partial suspensions of production and/or distribution; (5) suspension of marketing applications; and (6) enforcement actions, including injunctions and civil suits or criminal prosecution. Further, the FDA often requires post-marketing testing and surveillance to monitor the effects of approved products. The FDA and comparable international regulatory agencies may condition approval of our product candidates on the completion of such post-marketing clinical studies. These post-marketing studies may suggest that a product causes undesirable side effects or may present a risk to the patient. If data we collect from post-marketing studies suggest that one of our approved products may present an unacceptable safety risk, regulatory authorities could withdraw the product's approval, suspend production or place other marketing restrictions on that product. If regulatory sanctions are applied or if regulatory approval is delayed or withdrawn, our operating results and the value of our company may be adversely affected.

Regulatory approval for our currently marketed products is limited by the FDA and other regulators to those specific indications and conditions for which clinical safety and efficacy have been demonstrated.

Any regulatory approval of our products is limited to specific diseases and indications for which our products have been deemed safe and effective by the FDA. In addition to the FDA approval required for new formulations, any new indication for an approved product also requires FDA approval. If we are not able to obtain FDA approval for any desired future indications for our products, our ability to effectively market and sell our products may be reduced.

While physicians may choose to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those approved by regulatory authorities (called "off-label" uses), our ability to promote the products is limited to those indications that are specifically approved by the FDA. Although U.S. regulatory authorities generally do not regulate the behavior of physicians, they do restrict communications by companies on the subject of off-label use. If our promotional activities fail to comply with these regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, failure to follow FDA rules and guidelines relating to promotion and advertising can result in the FDA's refusal to approve a product, suspension or withdrawal of an approved product from the market, product recalls, fines, disgorgement of money, operating restrictions, civil lawsuits, injunctions or criminal prosecution.

We must comply with various laws in jurisdictions around the world that restrict certain marketing practices in the pharmaceutical and medical device industries. Failure to comply with such laws could result in penalties and have a material adverse effect on our business, financial condition and results of operations.

There are various laws in jurisdictions around the world that restrict particular marketing practices in the pharmaceutical and medical device industries. These laws include, but are not limited to, anti-kickback and false claims statutes, the Foreign Corrupt Practices Act and the UK Bribery Act. Our business activities may be subject to challenge under these laws, and any penalties imposed upon us could have a material adverse effect on our business and financial condition. Furthermore, we have significantly expanded our sales and marketing staff. Any expansion of sales and marketing efforts can increase the risks of noncompliance with these laws. Finally, the growth in our operations outside the United States, both directly and through third-party distributors, also has increased these risks.

## Table of Contents

In the United States, the federal health care program anti-kickback statute prohibits, among other activities, knowingly and willfully offering, paying, soliciting, or receiving compensation to induce, or in return for, the purchase, lease, order or arranging the purchase, lease or order of any health care product or service reimbursable under any federally financed health-care program. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. The exemptions and safe harbors for this statute are narrow, and practices that involve compensation intended to induce prescriptions, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not always meet all of the criteria for safe harbor protection.

The federal False Claims Act prohibits any person from knowingly presenting or causing to be presented a false claim or knowingly making or causing a false statement material to a false claim. Several pharmaceutical and health care companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the free product. Other companies have been prosecuted for causing false claims to be submitted because of these companies' marketing of a product for unapproved and non-reimbursable uses. Potential liability under the federal False Claims Act includes mandatory treble damages and significant per-claim penalties, currently set at \$5,500 to \$11,000 per false claim. The majority of states also have statutes or regulations similar to the federal anti-kickback statute and False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs; furthermore, in several states, these statutes and regulations apply regardless of the payer. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's product from reimbursement under government programs, debarment, criminal fines, and imprisonment.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (PPACA), also imposed new reporting requirements for pharmaceutical, biologic and device manufacturers with regard to payments or other transfers of value made to physicians and teaching hospitals. In addition, pharmaceutical, biologic and device manufacturers, with certain exceptions, are required to report and disclose investment interests held by physicians and their immediate family members during the preceding calendar year. Failure to submit required information may result in civil monetary penalties of up to \$150,000 per year (and up to \$1.0 million per year for "knowing failures") for all payments, transfers of value or ownership or investment interests not reported in an annual submission.

Further, the PPACA amends the intent requirement of the federal anti-kickback and criminal health care fraud statutes. This amendment provides that a person or entity no longer needs to have knowledge of these statutes or specific intent to violate them. In addition, the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

If not preempted by this federal law, several states currently require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and to report gifts and payments to individual physicians in those states. Depending on the state, legislation may prohibit various other marketing related activities, or require the posting of information relating to clinical studies and their outcomes. In addition, certain states, such as California, Nevada, Connecticut and Massachusetts, require pharmaceutical companies to implement compliance programs or marketing codes and several other states are considering similar proposals. Compliance with these laws is difficult and time consuming, and companies that do not comply with these state laws will face civil penalties.

## Table of Contents

# Government health care reform could increase our costs, which would adversely affect our revenue and results of operations.

Our industry is highly regulated and changes in law may adversely impact our business, operations or financial results. The PPACA is a broad measure intended to expand health care coverage within the United States, primarily through the imposition of health insurance mandates on employers and individuals and expansion of the Medicaid program. The reforms imposed by the law will significantly impact the pharmaceutical industry; however, the full effects of the PPACA will be unknown until all of these provisions are implemented and the Centers for Medicare and Medicaid Services and other federal and state agencies issue applicable regulations or guidance. Moreover, in the coming years, additional changes could be made to governmental health care programs that could significantly impact the success of our products or product candidates.

Reports of actual or perceived side effects and adverse events associated with our products, such as sepsis, could cause physicians and patients to avoid or discontinue use of our products in favor of alternative treatments.

Reports of side effects and adverse events associated with our products could have a significant adverse impact on the sale of our products. An example of a known risk associated with intravenous Remodulin is sepsis, which is a serious and potentially life-threatening infection of the bloodstream caused by a wide variety of bacteria. Intravenous prostacyclin analogues, such as intravenous Remodulin, are infused continuously through a catheter placed in a large vein in the patient's chest, and sepsis is a known risk associated with this type of delivery. As a result, sepsis is included as a risk in the Remodulin package insert, and the occurrence of sepsis is familiar to physicians who prescribe intravenously administered therapies. Concerns about bloodstream infections may affect a physician's decision to prescribe or a patient's willingness to use intravenous Remodulin.

## Negative attention from special interest groups may impair our business.

As is common with pharmaceutical and biotechnology companies, our early-stage research and development involves animal testing, which we conduct both directly and through contracts with third parties. Notwithstanding the vital role of animal research in the drug discovery and development process, certain special interest groups categorically object to the use of animals for research purposes. Historically, our research and development activities have not been the subject of significant animal rights media attention. However, research activities with animals have been the subject of adverse attention, generally including demonstrations near facilities operated by other companies in our industry. Any negative attention, threats or acts of vandalism directed against our animal research activities in the future could impede the operation of our business.

If any of the license or other agreements under which intellectual property rights are licensed to, or were acquired by us, are breached or terminated, our right to continue to develop, produce and sell the products covered by such agreements could be impaired or lost.

Our business depends upon our continuing ability to exploit our intellectual property rights in the drugs and other products that have been discovered and initially developed by others and those which we have commercialized and are developing further. These intellectual property rights have either been licensed to us or have been acquired by us. Under each of our product license agreements, we are granted a license to intellectual property owned by others that covers a drug or other product. Under each of our purchase agreements, we have rights to certain intellectual property. We may be required to license other intellectual property owned by third parties to continue to develop and commercialize our products.

# Table of Contents

This dependence on intellectual property developed by others involves the following risks:

We may be unable to obtain rights to intellectual property that we determine we need for our business at a reasonable cost or at all:

If any of our product licenses or purchase agreements are terminated, we may lose our rights to develop, make and sell the products to which such licenses or agreements relate;

Our license and purchase agreements generally provide the licensor or seller with the right to terminate the agreement in the event of a breach; for example, if we fail to pay royalties and other fees timely and do not cure the failure within a stated time period; and

If a licensor of intellectual property that we have rights to breaches its obligation or otherwise fails to maintain the intellectual property licensed, we may lose any ability to prevent others from developing or marketing similar products that are covered by such intellectual property. In addition, we may be forced to incur substantial costs to maintain the intellectual property ourselves or take legal action seeking to force the licensor to do so.

Certain agreements under which we acquired or licensed intellectual property rights may restrict our ability to develop related products in certain countries or for particular diseases and may impose other restrictions that affect our ability to develop and market related products in the most effective manner.

When we acquire or license intellectual property rights to drugs and other products that have been discovered and initially developed by others, these rights are frequently limited. For instance, our rights to market Adcirca are geographically limited to the United States. Furthermore, we cannot undertake any additional investigational work with respect to Adcirca in other indications of pulmonary hypertension without Lilly's prior approval. Provisions in our license and purchase agreements may impose other restrictions that affect our ability to develop and market products to which the intellectual property relates. For example, Lilly also has authority over all regulatory activities relating to Adcirca and has the right to determine the price at which we sell the drug.

Our intellectual property rights may not effectively deter competitors from developing competing products that, if successful, could have a material adverse effect on our revenues and profits.

The period under which our commercial and developmental therapies are protected by our patent rights is limited. Three of our U.S. patents covering our current methods of synthesizing and producing treprostinil, the active ingredient in Remodulin, Tyvaso and Orenitram, expire in October 2017, and a fourth will expire in 2028. We recently settled patent litigation with Sandoz and Teva, which will permit them to launch generic versions of Remodulin in the United States in June 2018 and December 2018, respectively, although they may be permitted to enter the market earlier under certain circumstances. We also have been granted one patent in the European Union and one patent in Japan, each of which covers our treprostinil synthesis and production methods and will expire in October 2018. Our three U.S. patents covering an improved diluent for Remodulin will expire in 2028 and 2029. Our U.S. patent covering intravenous administration of Remodulin with certain diluents expires in 2024. Our patents for Tyvaso covering methods of treating PAH by inhaled delivery will expire in the United States and in various countries throughout the world in 2018 and 2020, respectively. Our patents for Orenitram covering methods of use for treating PAH, orally administered formulations, controlled moisture storage and production methods and controlled release formulations will expire in the United States between 2024 and 2031 and in various countries throughout the world in 2024. The U.S. patent for Adcirca for the treatment of pulmonary hypertension will expire in November 2017.

We continue to conduct research into new methods to synthesize treprostinil and have pending U.S. and international patent applications and patents relating to such methods. However, we cannot be sure that these additional patents will effectively deter or delay competitors' efforts to bring new

## Table of Contents

products to market, or that additional patent applications will result in new patents. Upon the expiration of any of our patents, competitors may develop generic versions of our products and may market those generic versions at a lower price to compete with our products. Competitors may also seek to design around our patents prior to their expiration in an effort to develop competing products that do not infringe our patents. Prior to the expiration of our patents, third parties may challenge the validity of our patents, through patent litigation, proceedings before the U.S. Patent and Trademark Office or other applicable patent filing office, or other means.

The scope of any patent we hold may not deter competitors from developing a product that competes with the product we sell that is covered by the patent. Patent laws of foreign jurisdictions may not protect our patent rights to the same extent as the patent laws of the United States. In addition, we may be forced to incur substantial costs to defend the intellectual property rights conferred by our patents. Furthermore, our suppliers who have granted us exclusive rights may have inadequate intellectual property protections. Competitors also may attempt to invalidate our existing patents before they expire.

In addition to patent protection, we also rely on trade secrets to protect our proprietary know-how and other technological advances that we do not disclose to the public. We enter into confidentiality agreements with our employees and others to whom we disclose trade secrets and other confidential information. These agreements may not necessarily prevent our trade secrets from being used or disclosed without our authorization and confidentiality agreements may be difficult, time-consuming and expensive to enforce or may not provide an adequate remedy in the event of unauthorized disclosure. In addition, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such third party, or those to whom they communicate such technology or information, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our business and competitive position could be harmed.

The validity, enforceability and scope of certain of our patents covering Remodulin, Tyvaso and Orenitram are currently being challenged as a result of ANDA filings by generic drug companies and a petition for inter partes review. The outcome of current or future challenges with respect to the validity, enforceability, or scope of our patents could significantly reduce revenues from Remodulin, Tyvaso and Orenitram.

Both Sandoz and Teva filed ANDAs seeking FDA approval to market generic versions of Remodulin, and Watson has filed an ANDA seeking FDA approval to market a generic version of Tyvaso. We recently settled our litigation with Sandoz and Teva, which will permit them to launch their generic Remodulin products in the United States in June 2018 and December 2018, respectively, although they may be permitted to enter the market earlier under certain circumstances, and we have filed a lawsuit against Watson in the U.S. District Court for the District of New Jersey alleging patent infringement. In addition, in October 2015, SteadyMed filed a petition for inter partes review with the Patent Trial and Appeal Board of the United States Patent and Trademark Office seeking to invalidate one of our patents covering a method of making treprostinil that expires in 2028 and is listed in the Orange Book for Remodulin, Tyvaso, and Orenitram. In February 2016, we were notified that Actavis has filed an ANDA seeking FDA approval to market a generic version of Orenitram. For details on the status of these matters, please see Note 19 Litigation, to our consolidated financial statements *Item 3 Legal Proceedings* an Part II, Item 9B Other Information.

We may not prevail in our defense of our patent rights, and additional challenges from other ANDA filers or other competitors may surface with respect to Remodulin, Tyvaso and Orenitram. Our existing patents could be invalidated, found unenforceable or found not to cover one or more generic forms of Remodulin, Tyvaso or Orenitram. If any ANDA filer were to receive approval to sell a generic version of Remodulin, Tyvaso or Orenitram and/or prevail in any patent litigation, the affected product would become subject to increased competition and our revenue would decrease.

## Table of Contents

Third parties may allege that our patents are invalid, or that our products or services infringe their patents and other intellectual property rights, which could result in the payment of royalties. Payment of royalties would negatively affect our profits; furthermore, if we chose to contest these allegations, we could be subject to costly and time-consuming litigation or could lose the ability to continue to sell the related products.

Third parties may seek to invalidate or otherwise challenge our patents, through patent litigation and/or initiating proceedings, including re-examinations, *inter partes* reviews, post-grant reviews and interference proceedings, before the U.S. Patent and Trademark Office. We may initiate litigation to enforce or defend our patents or intellectual property rights; however, litigation can be time consuming, distracting to our operations, costly and may conclude unfavorably for us. In addition, the outcome of patent infringement litigation often is difficult to predict. If we are unsuccessful with respect to any future legal action in the defense of our patents and our patents are invalidated or determined to be unenforceable, our business could be negatively impacted. Even if our patents are determined to be valid or enforceable, it is possible that a competitor could circumvent our patents by effectively designing around the claims of our patents. Accordingly, our patents may not provide us with any competitive advantage.

To the extent third-party patents to which we currently do not hold licenses are necessary for us to manufacture, use or sell our products, we would need to obtain necessary licenses to prevent infringement. In the case of products or services that utilize intellectual property of strategic collaborators or other suppliers, such suppliers may have an obligation to secure the needed license to these patents at their cost. Otherwise, we would be responsible for the cost of these licenses. Royalty payments and other fees under these licenses would erode our profits from the sale of related products and services. Moreover, we may be unable to obtain these licenses on acceptable terms or at all. If we fail to obtain a required license or are unable to alter the design of the product to avoid infringing a third-party patent, we would be unable to continue to manufacture or sell related products.

If a third party commences legal action against us for infringement, or institutes proceedings challenging the validity of our patents, we could be compelled to incur significant costs to defend the action and our management's attention could be diverted, whether or not the action were to have any merit. We cannot be certain that we could prevail in the action, and an adverse judgment or settlement resulting from the action could require us to pay substantial amounts in damages for infringement or substantial amounts to obtain a license to continue to use the intellectual property that is the subject of the infringement claim.

## We may not maintain adequate insurance coverage to protect us against significant product liability claims.

The testing, manufacturing, marketing, and sale of drugs and diagnostics involve product liability risks. We may not be able to maintain our current product liability insurance at an acceptable cost, if at all. In addition, our insurance coverage may not be adequate for all potential claims. If claims or losses significantly exceed our liability insurance coverage, we may experience financial hardship or potentially be forced out of business.

If we fail to attract and retain key management and qualified scientific and technical personnel, we may not be able to achieve our business objectives.

Members of our management team, including our founder, Chairman and Co-Chief Executive Officer, Dr. Martine Rothblatt, and our President and Co-Chief Executive Officer, Dr. Roger Jeffs, play a critical role in defining our business strategy and maintaining our corporate culture. The loss of the services and leadership of Dr. Rothblatt, Dr. Jeffs or any other members of our senior management team could have an adverse effect on our business. We do not maintain key person life insurance on our senior management team members. In addition, effective succession planning is important to our long-term success. Failure to identify, hire and retain suitable successors for members of our senior

## Table of Contents

management team and to transfer knowledge effectively could impede the achievement of our business objectives. Our future success also depends on our ability to attract and retain qualified scientific and technical personnel. Competition for skilled scientific and technical personnel in the biotechnology and pharmaceutical industries is intense. Furthermore, our compensation arrangements may not be sufficient to attract new qualified scientific and technical employees or retain such core employees. If we fail to attract and retain such employees, we may not be successful in developing and commercializing new therapies for PAH and other diseases.

#### Improper handling of hazardous materials used in our activities could expose us to significant remediation liabilities.

Our research and development and manufacturing activities involve the controlled use of chemicals and hazardous substances and we are expanding these activities in both scale and location. In addition, patients may dispose of our products using means we do not control. Such activities subject us to numerous federal, state, and local environmental and safety laws and regulations that govern the management, storage and disposal of hazardous materials. Compliance with current and future environmental laws and regulations can require significant costs; furthermore, we can be subject to substantial fines and penalties in the event of noncompliance. The risk of accidental contamination or injury from these materials cannot be completely eliminated. Furthermore, once chemical and hazardous materials leave our facilities, we cannot control the manner in which such hazardous waste is disposed of by our contractors. In the event of an accident, we could be liable for substantial civil damages or costs associated with the cleanup of the release of hazardous materials. Any related liability could have a material adverse effect on our business.

#### We may encounter substantial difficulties managing our growth relative to product demand.

We have spent considerable resources building and expanding our offices, laboratories and production facilities. However, our facilities could be insufficient to meet future demand for our products. Conversely, we may have excess capacity at our facilities if future demand falls short of our projections, or if we do not receive regulatory approvals for the products we intend to produce at our facilities. Constructing our facilities is expensive and our ability to satisfactorily recover our investment will depend on sales of the products manufactured at these facilities in sufficient volume. If we do experience substantial sales growth, we may have difficulty managing inventory levels as marketing new therapies is complicated and gauging future demand can be difficult and uncertain until we possess sufficient post-launch sales experience.

# If we need additional financing and cannot obtain it, our product development and sales efforts may be limited.

In January 2016, we entered into a Credit Agreement (the 2016 Credit Agreement) with Wells Fargo Bank, National Association (Wells Fargo), as administrative agent and a swingline lender, and various other lender parties, providing for an unsecured revolving credit facility of up to \$1.0 billion (the Revolving Facility). The Revolving Facility will mature five years after the closing date of the 2016 Credit Agreement, subject to the lenders' ability to extend the maturity date by one year if we request such an extension in accordance with the terms of the 2016 Credit Agreement.

Notwithstanding the 2016 Credit Agreement, we may be required to seek additional sources of financing to meet unplanned or planned expenditures. Unplanned expenditures could be significant and may result from necessary modifications to product development plans or product offerings in response to difficulties encountered with clinical trials. We may also face unexpected costs in preparing products for commercial sale, or in maintaining sales levels of our currently marketed therapeutic products. In addition, the 2016 Credit Agreement contains affirmative and negative covenants that, among other things, limit our ability to incur additional indebtedness. If we are unable to obtain additional funding

## Table of Contents

on commercially reasonable terms or at all, we may be compelled to delay clinical studies, curtail operations or obtain funds through collaborative arrangements that may require us to relinquish rights to certain products or potential markets.

We may require additional financing to meet significant future obligations. For example, awards granted under our Share Tracking Award Plans (which we collectively refer to as the STAP) entitle participants to receive in cash an amount equal to the appreciation in the price of our common stock, which is calculated as the positive difference between the closing price of our common stock on the date of exercise and the date of grant. Consequently, our STAP may require significant future cash payments to participants to the extent the price of our common stock appreciates and the number of vested STAP awards increases over time. If we do not have sufficient funds to meet such obligations or the ability to secure alternative sources of financing, we could be in default, face litigation and/or lose key employees, which could have a material adverse effect on our business.

We may not be able to generate sufficient cash to service our indebtedness, which may have a material adverse effect on our financial position, results of operations and cash flows. In addition, we may be forced to take other actions to satisfy our obligations in connection with our indebtedness, which actions may not be successful.

We may borrow up to \$1.0 billion under the 2016 Credit Agreement. Our ability to make payments on or refinance our debt obligations, including any future debt that we may incur, will depend on our financial condition and operating performance, which are subject to prevailing economic and competitive conditions and to certain financial, business, legislative, regulatory and other factors beyond our control. We may be unable to maintain a level of cash flows from operating activities sufficient to permit us to pay the principal, premium, if any, and interest on our indebtedness. Our inability to generate sufficient cash flows to satisfy our debt obligations would materially and adversely affect our financial position and results of operations.

If we cannot repay or refinance our debt as it becomes due, we could be forced to take disadvantageous actions, including reducing or delaying investments and capital expenditures, disposing of material assets or operations, seeking additional debt or equity capital or restructuring or refinancing our indebtedness. We may not be able to effect any such alternative measures, if necessary, on commercially reasonable terms or at all and, even if successful, such actions may not be sufficient for us to meet any such debt service obligations. In addition, our ability to withstand competitive pressures and to react to changes in our industry could be impaired.

In addition, the 2016 Credit Agreement contains restrictive covenants that limit our ability to take certain actions including, among other things, our ability to incur additional indebtedness, grant liens, merge or consolidate; liquidate, wind up or dissolve; or sell all or substantially all of our assets. Our failure to comply with the covenants in the 2016 Credit Agreement could result in an event of default which, if not cured or waived, could result in the acceleration of all amounts due under the 2016 Credit Agreement.

Information technology security breaches and other disruptions could compromise our information and expose us to legal responsibility which would cause our business and reputation to suffer.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, our proprietary business information and that of our suppliers, customers and business partners, and personally identifiable information. The secure maintenance of this information is critical to our operations and business strategy. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Such breaches could compromise sensitive and confidential information stored on our networks and expose such information to public disclosure, loss or theft. Any access, disclosure or

## Table of Contents

other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, disruption of our operations, and damage to our reputation which could adversely affect our business.

#### Risks Related to Our Common Stock

## The price of our common stock can be highly volatile and may decline.

The price of common stock can be highly volatile within the pharmaceutical and biotechnology sector. Consequently, there can be significant price and volume fluctuations in the market that may not relate to operating performance. The following table sets forth the high and low closing prices of our common stock for the periods indicated:

	High	Low
January 1, 2015 - December 31, 2015	\$ 188.56	\$ 119.57
January 1, 2014 - December 31, 2014	\$ 136.16	\$ 86.14
January 1, 2013 - December 31, 2013	\$ 114.51	\$ 51.64

The price of our common stock could decline sharply due to the following factors, among others:

Failure to meet our estimates or expectations, or those of securities analysts;

Quarterly and annual financial results;

Timing of enrollment and results of our clinical trials;

Announcements by us or others regarding generic or other challenges to the intellectual property relating to our products, including developments with respect to the ANDA filed by a generic drug company relating to certain of our Tyvaso patents and to our pending lawsuit defending our patent rights, and the *inter partes* review petition filed by SteadyMed challenging the validity of one of the patents listed in the Orange Book for Remodulin, Tyvaso and Orenitram;

Physician, patient, investor or public concerns regarding the efficacy and/or safety of products marketed or being developed by us or by others;

Changes in, or new legislation and regulations affecting reimbursement of, our therapeutic products by Medicare, Medicaid or other government payers, and changes in reimbursement policies of private health insurance companies, and negative publicity surrounding the cost of high-priced therapies;

Announcements by us or others of technological innovations or new products or announcements regarding our existing products, including in particular the development of new, competing PAH therapies;

Substantial sales of our common stock by us or our existing shareholders;

Future issuances of common stock by us or any other activity which could be viewed as being dilutive to our shareholders;

Rumors among, or incorrect statements by, investors and/or analysts concerning our company, our products, or our operations;

Failure to obtain or maintain regulatory approvals from the FDA or international regulatory agencies;

## **Table of Contents**

Discovery of previously unknown problems with our marketed products, or problems with our production, regulatory, compliance, promotional, marketing or sales activities that result in regulatory penalties or restrictions on our products, up to the withdrawal of our products from the market;

Accumulation of significant short positions in our common stock by hedge funds or other investors or the significant accumulation of our common stock by hedge funds or other institutional investors with investment strategies that may lead to short-term holdings; and

General market conditions.

# We may fail to meet third-party projections for our revenues or profits.

Many securities analysts publish quarterly and annual projections of our revenues and profits. Such projections are inherently subject to uncertainty. As a result, actual revenues and profits may fail to meet these projections. Even minor variations in reported revenues and profits compared to securities analysts' expectations could have a significant adverse impact on the price of our common stock.

#### Sales or issuances of our common stock may depress our stock price.

The price of our common stock could decline if: (1) we issue common stock to raise capital or to acquire a license or business; (2) our shareholders transfer ownership of our common stock, or sell substantial amounts of our common stock in the public market; or (3) our investors become concerned that substantial sales of our common stock may occur. A decrease in the price of our common stock could make it difficult for us to raise capital or fund acquisitions through the issuance of our stock.

## Our share repurchases may affect the value of our common stock.

In recent years, our Board of Directors has authorized several programs to repurchase our common stock, including a \$500.0 million share repurchase program effective during the one-year period commencing January 1, 2016. The price of our common stock may, in part, reflect expectations that we will use all of the funds authorized under our repurchase program to repurchase shares or that additional repurchase programs will be authorized once the current program terminates. Our current share repurchase program does not obligate us to acquire any specific number of shares and any further repurchase programs are subject to the approval of our Board of Directors. If we fail to meet analyst or investor expectations regarding repurchase programs, our stock price may decline.

Provisions of Delaware law and our amended and restated certificate of incorporation, fourth amended and restated by-laws, shareholder rights plan and employment and license agreements, among other things, could prevent or delay a change of control or change in management that may be beneficial to our public shareholders.

Certain provisions of Delaware law and our amended and restated certificate of incorporation, fourth amended and restated by-laws and shareholder rights plan may prevent, delay or discourage:

A merger, tender offer or proxy contest;

The assumption of control by a holder of a large block of our securities; and/or

The replacement or removal of current management by our shareholders.

For example, our amended and restated certificate of incorporation divides our Board of Directors into three classes. Members of each class are elected for staggered three-year terms. This provision may make it more difficult for shareholders to replace the majority of directors. It may also deter the accumulation of large blocks of our common stock by limiting the voting power of such blocks.

## Table of Contents

Non-competition and all other restrictive covenants in most of our employment agreements will terminate upon a change of control that is not approved by our Board.

Similarly, a change of control, under certain circumstances, could also result in an acceleration of the vesting of outstanding STAP awards and stock options. This, together with any increase in our stock price resulting from the announcement of a change of control, could make an acquisition of our company significantly more expensive to the purchaser. We also have a broad-based change of control severance program, under which employees may be entitled to severance benefits in the event they are terminated without cause (or they terminate their employment for good reason) following a change of control. This program could also increase the cost of acquiring our company.

We enter into certain license agreements that generally prohibit our counterparties or their affiliates from taking necessary steps to acquire or merge with us, directly or indirectly throughout the term of these agreements, plus a specified period thereafter. We are also party to certain license agreements that restrict our ability to assign or transfer the rights licensed to us to third parties, including parties with whom we wish to merge, or those attempting to acquire us. These agreements often require that we obtain prior consent of the counterparties to these agreements if we are contemplating a change of control. If these counterparties withhold consent, related agreements could be terminated and we would lose related license rights. For example, both Lilly and Toray have the right to terminate our license agreements relating to Adcirca and esuberaprost, respectively, in the event of certain change of control transactions. These restrictive change of control provisions could impede or prevent mergers or other transactions that could benefit our shareholders.

Because we do not intend to pay cash dividends, our shareholders must rely on stock appreciation for any return on their investment in us.

We have never declared or paid cash dividends on our common stock. Furthermore, we do not intend to pay cash dividends in the future and our 2016 Credit Facility contains covenants that may restrict us from doing so. As a result, the return on an investment in our common stock will depend entirely upon the future appreciation in the price of our common stock. There can be no assurances that our common stock will provide a return to investors.

#### ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

# ITEM 2. PROPERTIES

Maryland We own a 232,000 square foot combination laboratory and office building complex in Silver Spring, Maryland that serves as our co-headquarters and is used for the synthesis of treprostinil, the active ingredient in Remodulin and Tyvaso, and treprostinil diolamine, the active ingredient in Orenitram, as well as the production of Remodulin and Tyvaso and Unituxin. We also own several other buildings in Silver Spring used principally for office and laboratory space.

North Carolina We own a 380,000 square foot combination manufacturing facility and office building in Research Triangle Park, North Carolina (RTP facility), which serves as our co-headquarters and is occupied by our clinical research and development, commercialization and our logistics and manufacturing personnel. We warehouse and distribute Remodulin, Tyvaso and Orenitram and produce Orenitram at this location. In 2012, we acquired a 132-acre property containing approximately 312,000 square feet of building space adjacent to our RTP facility, which we use for our research, development and production facilities relating to our lung regeneration program, office space and for future expansion.

# Table of Contents

Europe We own an office building near London, England which serves as our European headquarters. In Germany, we lease a warehouse where we maintain inventory of components for our Tyvaso Inhalation System. The German facility includes office and laboratory space.

District of Columbia We own two adjacent buildings in Washington, D.C., which serve as office space.

Florida We own office buildings in Satellite Beach and Melbourne, Florida.

We believe that these facilities, along with various other owned and leased facilities, are adequate for our current operations and that additional land and facilities for future expansion are reasonably available.

# ITEM 3. LEGAL PROCEEDINGS

Please refer to Note 19 *Litigation*, to our consolidated financial statements contained elsewhere in this Annual Report on Form 10-K, which is incorporated herein by reference.

# ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

56

## **Table of Contents**

## **PART II**

# ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

## **Market Information**

Our common stock (and associated preferred stock purchase rights) trades on the NASDAQ Global Select Market under the symbol "UTHR". The table below sets forth the high and low closing prices for our common stock for the periods indicated:

	20	15		20	14	
	High		Low	High		Low
January 1 - March 31	\$ 179.51	\$	124.93	\$ 113.39	\$	90.67
April 1 - June 30	\$ 188.56	\$	159.69	\$ 107.81	\$	86.14
July 1 - September 30	\$ 179.15	\$	131.24	\$ 136.16	\$	86.44
October 1 - December 31	\$ 160.91	\$	119.57	\$ 134.80	\$	122.11
Number of Holders						

As of February 12, 2016, there were 38 holders of record of our common stock.

# **Dividend Policy**

We have never paid and have no present intention to pay cash dividends on our common stock in the foreseeable future and our 2016 Credit Facility contains covenants that may restrict us from doing so. We intend to retain any earnings for use in our business operations.

# **Issuer Purchases of Equity Securities**

We did not repurchase any of our outstanding equity securities during the three months ended December 31, 2015, as the authorization under our previous share repurchase program was fully exhausted in August 2015. On October 15, 2015, we announced that our Board of Directors authorized a new share repurchase program for up to \$500.0 million in aggregate repurchases, which is effective from January 1, 2016 through December 31, 2016.

# Table of Contents

# Comparison of Five-Year Total Cumulative Shareholder Return

The following chart shows the performance from December 31, 2010 through December 31, 2015 of our common stock, compared with an investment in the stocks represented in each of the NASDAQ U.S. Benchmark TR Index and the NASDAQ ICB: 4577 Pharmaceutical Stock Index, assuming the investment of \$100 at the beginning of the period and the reinvestment of dividends, if any.

# ITEM 6. SELECTED FINANCIAL DATA

The following selected consolidated financial data should be read in conjunction with our consolidated financial statements and the notes accompanying the consolidated financial statements and *Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations* included in this Annual Report on Form 10-K. The historical results are not necessarily indicative of results to be expected for future periods. The following information is presented in thousands, except per share data.

	Year Ended December 31,											
		2015		2014		2013		2012		2011		
Consolidated Statements of												
Operations Data:												
Revenues	\$	1,465,761	\$	1,288,519	\$	1,116,984	\$	916,076	\$	743,183		
Operating income	\$	699,015	\$	538,800	\$	292,499	\$	421,646	\$	317,782		
Income from continuing operations	\$	651,639	\$	340,074	\$	174,560	\$	304,442	\$	217,243		
Income from discontinued operations,												
net of tax	\$		\$		\$		\$		\$	625		
Net income	\$	651,639	\$	340,074	\$	174,560	\$	304,442	\$	217,868		
Net income per common share:												
Basic <sup>(1)</sup>	\$	14.17	\$	7.06	\$	3.49	\$	5.84	\$	3.81		
Diluted <sup>(1)</sup>	\$	12.72	\$	6.28	\$	3.28	\$	5.71	\$	3.67		
			58									

## **Table of Contents**

	As of December 31,											
		2015		2014		2013		2012		2011		
Consolidated Balance Sheet Data:												
Cash, cash equivalents and marketable												
investments	\$	991,774	\$	818,197	\$	1,142,037	\$	784,931	\$	747,378		
Total assets	\$	2,184,445	\$	1,884,410	\$	2,087,567	\$	1,626,595	\$	1,518,079		
Other liabilities	\$	143,974	\$	114,526	\$	95,582	\$	354,977	\$	346,132		
Total stockholders' equity	\$	1,588,552	\$	1,242,356	\$	1,259,274	\$	1,083,981	\$	948,488		

(1)

Refer to Note 11 Stockholders' Equity Earnings Per Common Share to our consolidated financial statements contained in this Annual Report on Form 10-K for the computation of basic and diluted net income per share.

#### ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion should be read in conjunction with our consolidated financial statements and related notes to the consolidated financial statements included in this Annual Report on Form 10-K. The following discussion contains forward-looking statements made pursuant to the safe harbor provisions of Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. These statements are based on our expectations about future outcomes and are subject to risks and uncertainties that could cause actual results to differ materially from anticipated results. Factors that could cause or contribute to such differences include those described under *Part I*, *Item 1A Risk Factors* included in this Annual Report on Form 10-K and factors described in other cautionary statements, cautionary language and risk factors set forth in other documents we filed with the Securities and Exchange Commission. We undertake no obligation to publicly update forward-looking statements, whether as a result of new information, future events or otherwise.

# Overview

Our key therapeutic products and product candidates include:

*Prostacyclin analogues (Remodulin®, Tyvaso®, Orenitram® and esuberaprost):* stable synthetic forms of prostacyclin, an important molecule produced by the body that has powerful effects on blood vessel health and function;

*Phosphodiesterase type 5 (PDE-5) inhibitor (Adcirca®):* a molecule that acts to inhibit the degradation of cyclic guanosine monophosphate (cyclic GMP) in cells. Cyclic GMP is activated by nitric oxide (NO), a naturally occurring substance in the body that mediates the relaxation of vascular smooth muscle;

Monoclonal antibody for oncologic applications (Unituxin®): an antibody that binds to cancerous tumors and destroys the cancer cells through a mechanism called antibody-dependent cell mediated cytotoxicity; and

Organ transplantation: engineered lungs and lung tissue, which we are developing using xenotransplantation and regenerative medicine technologies, for transplantation in patients suffering from PAH and other lung diseases. Although our primary focus is on engineered lungs, we are also developing technology for other engineered organs, such as kidneys and hearts. Through our wholly-owned subsidiary, Lung Biotechnology PBC, we are also developing technologies to improve outcomes for lung transplant recipients and to increase the supply of donor lungs through ex-vivo lung perfusion.

# Table of Contents

We concentrate substantially all of our research and development efforts on the preceding key therapeutic products and product candidates.

We currently market and sell the following commercial products:

Remodulin (treprostinil) Injection (Remodulin). Remodulin, a continuously-infused formulation of the prostacyclin analogue treprostinil, is approved by the U.S. Food and Drug Administration (FDA) for subcutaneous (under the skin) and intravenous (in the vein) administration. Remodulin is indicated to diminish symptoms associated with exercise in World Health Organization (WHO) Group 1 PAH patients. Remodulin has also been approved in various countries outside of the United States.

*Tyvaso* (*treprostinil*) *Inhalation Solution* (*Tyvaso*). Tyvaso, an inhaled formulation of treprostinil, is approved by the FDA to improve exercise ability in WHO Group 1 PAH patients.

*Orenitram (treprostinil) Extended-Release Tablets (Orenitram).* In December 2013, the FDA approved Orenitram, a tablet dosage form of treprostinil, for the treatment of PAH in WHO Group 1 PAH patients to improve exercise capacity. We commenced sales of Orenitram during the second quarter of 2014.

Adcirca (tadalafil) Tablets (Adcirca). We acquired exclusive commercialization rights to Adcirca, an oral PAH therapy, in the United States from Eli Lilly and Company (Lilly). Adcirca is approved by the FDA to improve exercise ability in WHO Group 1 PAH patients.

*Unituxin (dinutuximab) Injection (Unituxin).* In March 2015, the FDA approved Unituxin in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF), interleukin-2 (IL-2), and 13-cis-retinoic acid (RA), for the treatment of pediatric patients with high-risk neuroblastoma who achieve at least a partial response to prior first-line multiagent, multimodality therapy. We commenced U.S. sales of Unituxin in the third quarter of 2015. We received European Medicines Agency (EMA) approval during the third quarter of 2015.

# Revenues

Our net product sales consist entirely of sales of our five commercial products: Remodulin, Tyvaso, Adcirca, Orenitram and Unituxin.

We have entered into separate, non-exclusive distribution agreements with Accredo Health Group, Inc. (Accredo) and CVS Caremark (Caremark) in the United States, to distribute Remodulin, Tyvaso and Orenitram. We also sell Remodulin to distributors internationally. In the second quarter of 2015, we entered into an exclusive distribution agreement with ASD Specialty Healthcare, Inc. (ASD), an affiliate of AmerisourceBergen Corporation, to distribute Unituxin in the United States. We sell Addirca through Lilly's pharmaceutical wholesaler network at a wholesale price determined by Lilly, which Lilly generally increases two or three times per year. Most recently, Lilly increased the price of Addirca by 9.9 percent effective May 14, 2015 and by another 9.9 percent effective December 1, 2015.

Under our distribution agreements, we sell Unituxin and each of our treprostinil-based products to these distributors at a transfer price that we establish. We pay Accredo, Caremark and ASD fees for services provided in connection with the distribution and support of these products. Historically, we have generally increased the price of Tyvaso annually by 4.9 percent, and the last price increase became effective on January 1, 2015. The price of Remodulin has not been increased since 2010. We have not increased the price of Orenitram or Unituxin since their launch in the second quarter of 2014 and the third quarter of 2015, respectively.

We require our distributors to maintain reasonable levels of inventory reserves of our treprostinil-based products as the interruption of Remodulin, Tyvaso or Orenitram therapy can be life threatening. Our distributors typically place monthly orders based on estimates of future demand and contractual

## Table of Contents

minimum inventory requirements. As a result, net product sales of Remodulin, Tyvaso and Orenitram can vary depending on the timing and magnitude of these orders and may not precisely reflect patient demand.

We recognize revenues net of: (1) estimated rebates; (2) prompt pay discounts; (3) allowances for sales returns; and (4) distributor fees. We estimate our liability for rebates based on an analysis of historical levels of rebates to both Medicaid and commercial third-party payers after considering the impact of sales trends, changes in government and commercial rebate programs and any anticipated changes in our products' pricing. In addition, we determine our obligation for prescription drug discounts required for Medicare Part D patients within the coverage gap based on estimates of the number of Medicare Part D patients and the period such patients will remain within the coverage gap. We provide prompt pay discounts to customers that pay amounts due within a specific time period and base related estimates on observed historical customer payment behavior. We derive estimates relating to our allowance for returns of Adcirca from actual return data accumulated since the drug's launch in 2009. We also compare patient prescription data for Adcirca to product sales on a quarterly basis to ensure a reasonable relationship between prescription and sales trends. To date, we have not identified any unusual patterns in the volume of prescriptions relative to sales that would warrant reconsideration of our methodology for estimating Adcirca returns. Remodulin, Tyvaso and Orenitram are distributed in the United States under separate contracts with substantially similar terms, which include exchange rights in the event that product is damaged during shipment or expires. The allowance for exchanges for Remodulin and Tyvaso is based on the historical rate of product exchanges, which has been negligible and immaterial. Furthermore, we anticipate minimal exchange activity in the future for Remodulin, Tyvaso and Orenitram since we typically sell these products with a remaining shelf life in excess of one year and our distributors generally carry a thirty- to sixty-day supply of our products at any given time. As a result, we do not record reserves for exchanges for Remodulin, Tyvaso and Orenitram at the time of sale. Lastly, we pay our distributors for contractual services rendered and accrue for related fees based on contractual rates applied to the estimated units of service provided by distributors for a given financial reporting period.

# Generic Competition

We have settled litigation with Sandoz and Teva relating to abbreviated new drug applications (ANDAs) seeking FDA approval to market generic versions of Remodulin before the expiration of certain of our U.S. patents. Under the terms of our settlement agreements, Sandoz and Teva will be permitted to market their generic versions of Remodulin in the United States beginning in June 2018 and December 2018, respectively, although they may be permitted to enter the market earlier under certain circumstances. We are engaged in litigation with Watson Laboratories, Inc. (Watson), contesting its ANDA to market a generic version of Tyvaso before the expiration of certain of our U.S. patents in November 2018 and December 2028. Finally, SteadyMed Ltd. (SteadyMed) has recently filed a petition for *inter partes* review seeking to invalidate one of our patents that expires in December 2028 and covers treprostinil, which is the active ingredient in Remodulin, Tyvaso and Orenitram. SteadyMed has announced that it is developing a product called Trevyent , which is a single-use, pre-filled pump being developed to deliver a two-day supply of treprostinil subcutaneously using its PatchPump® technology. In January 2016, SteadyMed announced that Trevyent has been granted orphan drug designation by the FDA for the treatment of PAH. In February 2016, we received notice that Actavis Laboratories FL, Inc. (Actavis) filed an ANDA seeking FDA approval to market a generic version of the 2.5 mg strength of Orenitram. For further details, please see Note 19 *Litigation*, to our consolidated financial statements *Item 3 Legal Proceedings* and *Part II, Item 9B Other Information*.

As a result of our settlements with Sandoz and Teva, we expect to see generic competition for Remodulin from these companies beginning in June 2018 and December 2018, respectively. This increased competition could reduce our net product sales and profits. In addition, while we intend to

## Table of Contents

vigorously enforce our intellectual property rights relating to our products, there can be no assurance that we will prevail in defending our patent rights, or that additional challenges from other ANDA filers or other challengers will not surface with respect to our products. Our patents could be invalidated, found unenforceable or found not to cover one or more generic forms of Remodulin, Tyvaso or Orenitram. If any ANDA filer were to receive approval to sell a generic version of Remodulin, Tyvaso or Orenitram and/or prevail in any patent litigation, the affected product(s) would become subject to increased competition which could reduce our sales.

Certain patents for Revatio®, a PDE-5 inhibitor marketed by Pfizer, Inc. for treatment of PAH, expired in 2012, leading several manufacturers to launch generic formulations of sildenafil citrate, the active ingredient in Revatio. Generic sildenafil's lower price relative to Adcirca could lead to pressure from payers to use generic products within the same class of therapy initially, which could erode Adcirca's market share and limit its potential sales. Although we believe Adcirca's once-daily dosing regimen provides a significant advantage over generic sildenafil's multiple dosing regimen, government payers and private insurance companies may favor the use of less expensive generic sildenafil over Adcirca. Thus far, we have not observed any measurable impact of generic sildenafil on sales of Adcirca; however, circumstances could change over time and our revenues could be adversely impacted. The U.S. patent for Adcirca for the treatment of pulmonary hypertension will expire in November 2017, following which we expect to see generic competition for Adcirca.

Patent expiration and generic competition for any of our commercial PAH products could have a significant, adverse impact on our revenues and profits, and is inherently difficult to predict. For additional discussion, please refer to the risk factor entitled, *Our intellectual property rights may not effectively deter competitors from developing competing products that, if successful, could have a material adverse effect on our revenues and profits*, contained in *Part I, Item 1A Risk Factors* included in this Annual Report on Form 10-K.

## **Operating Expenses**

Since our inception, we have devoted substantial resources to our various clinical trials and other research and development efforts, which are conducted both internally and through third parties. From time to time, we also license or acquire additional technologies and compounds to be incorporated into our development pipeline.

Our operating expenses include the following costs:

Research and Development

Our research and development expenses primarily include costs associated with the research and development of products and post-marketing research commitments. These costs generally include share-based compensation and salary-related expenses for research and development functions, professional fees for preclinical and clinical studies, costs associated with clinical manufacturing, facilities-related expenses and regulatory costs. Expenses also include costs for third-party arrangements, including upfront fees and milestone payments required under license arrangements for therapies under development.

Selling, General and Administrative

Our selling, general and administrative expenses primarily include costs associated with the commercialization of approved products and general and administrative costs to support our operations. Selling expenses generally include share-based compensation, salary-related expenses, product marketing and sales operations costs, and other costs incurred to support our sales efforts. General and administrative expenses include our core corporate support functions such as human resources, finance and legal, external costs such as insurance premiums, legal fees, grants to non-affiliated, not-profit organizations, and other professional service fees.

## Table of Contents

# Cost of Product Sales

Cost of product sales comprise: (1) costs to produce and acquire products sold to customers; (2) royalty payments under license agreements granting us rights to sell related products; and (3) direct and indirect distribution costs incurred in the sale of products. We acquired the rights to sell our commercial products through license and assignment agreements with the original developers of these products. These agreements obligate us to pay royalties based on specified percentages of our net product sales from related products. We paid GlaxoSmithKline PLC (Glaxo) a royalty of ten percent of net product sales of our treprostinil-based products (Remodulin, Tyvaso and Orenitram) until October 2014, when the patents we acquired from Glaxo expired. We no longer have any royalty obligations for Remodulin or Tyvaso, and our only remaining royalty obligation on Orenitram sales is a single-digit royalty relating to technology used in its formulation. We pay a five percent royalty to Lilly on net product sales of Adcirca. We have no royalty obligation for sales of Unituxin.

We produce our primary supply of Remodulin, Tyvaso, Orenitram and Unituxin at our own facilities. In particular, we synthesize treprostinil, the active ingredient in Remodulin and Tyvaso, and treprostinil diolamine, the active ingredient in Orenitram, at our facility in Silver Spring, Maryland. We also produce finished Tyvaso, Remodulin, and Unituxin at our Silver Spring facility. We produce Orenitram and we package, warehouse and distribute Remodulin, Tyvaso, Orenitram and Unituxin, at our facility in Research Triangle Park, North Carolina. We intend to use our own facilities to produce our primary supply of Remodulin, Tyvaso, Unituxin and Orenitram. We utilize third-party contract manufacturers to supplement our Remodulin and Tyvaso production capacity and mitigate the risk of shortages and we are working to obtain FDA approval of a third party to serve as an additional producer of Orenitram and Unituxin. We engage a third-party contract manufacturer to produce the Tyvaso Inhalation System. We began selling Orenitram during 2014. Typical of the initial commercial activities of a newly-launched product, Orenitram's cost of product sales as a percentage of its net product sales is significantly higher than that of our other commercial products. We expect that as Orenitram's sales increase, its cost of product sales as a percentage of total revenue will decrease to levels similar to our other treprostinil-based commercial products.

Lilly manufactures Adcirca. We take title to Adcirca upon its manufacture and bear any losses related to the storage, distribution and sale of Adcirca.

## Share-Based Compensation

We have granted awards under our share tracking award plans (STAP) and stock options under our equity incentive plans. Our operating expenses and net income are often materially impacted by the recognition of share-based compensation expense (benefit) associated with STAP awards and potential stock option grants containing a market or performance condition, as the fair value of these awards varies with the changes in our stock price. The fair values of STAP awards and potential stock option grants are measured using inputs and assumptions under the Black-Scholes-Merton model that can materially impact the amount of share-based compensation expense (benefit) for a given period.

We account for STAP awards as liabilities because they are settled in cash. As such, we must re-measure the fair value of STAP awards at the end of each financial reporting period until the awards are no longer outstanding. Changes in our STAP-related liability resulting from such re-measurements are recorded as adjustments to share-based compensation expense (benefit) and can create substantial volatility within our operating expenses from financial reporting period to period. The following factors, among others, have a significant impact on the amount of share-based compensation expense (benefit) recognized in connection with the STAP from period to period: (1) volatility in the price of our common stock (specifically, increases in the price of our common stock will generally result in an increase in our STAP liability and related compensation expense, while decreases in our stock price will

## Table of Contents

generally result in a reduction in our STAP liability and related compensation expense); (2) changes in the number of outstanding awards; and (3) changes in the number of vested and unvested awards.

In June 2015, our shareholders approved the United Therapeutics Corporation 2015 Stock Incentive Plan (the 2015 Plan). Following the approval of the 2015 Plan, which authorizes the grant of up to 6,150,000 shares of our common stock, we have ceased granting STAP awards and modified our equity compensation programs to grant stock options to employees and non-employee directors who previously received STAP awards. No further awards will be granted under our STAP plan or our previous equity plan, the Amended and Restated Equity Incentive Plan (the 1999 Plan).

Through December 31, 2014, we were contractually obligated to award stock options each year to our Chairman and Co-Chief Executive Officer, Dr. Rothblatt, based on a formula tied to the growth (if any) in our market capitalization. These awards were granted at year-end under the 1999 Plan, and vested immediately upon grant. We accrued compensation expense for Dr. Rothblatt's estimated stock option grant when we determined that it was probable that the performance criteria would be met. In 2015, Dr. Rothblatt's long term incentive compensation program is similar to our other employees in that she will be eligible for an annual grant of performance-based stock options based on the achievement of our annual corporate milestones, which vest over a four-year period from the grant date. Accordingly, we did not record any share-based compensation expense in 2015 for awards to Dr. Rothblatt as her annual grant of performance-based stock options will be granted in March 2016 based upon 2015 performance.

#### **Major Research and Development Projects**

Our major research and development projects focus on: (1) the use of prostacyclin analogues and other therapies to treat cardiopulmonary diseases; (2) monoclonal antibodies to treat cancer; and (3) organ transplantation technologies.

#### Cardiopulmonary Disease Projects

Remodulin Implantable System

In 2009, we entered into an agreement with Medtronic, Inc. (Medtronic) providing us exclusive rights in the United States, the United Kingdom, Canada, France, Germany, Italy and Japan to develop Medtronic's proprietary intravascular infusion catheter to be used with its SynchroMed® II implantable infusion pump and related infusion system components (together referred to as the Remodulin Implantable System) in order to deliver Remodulin for the treatment of PAH. If the Remodulin Implantable System is successful, it could reduce many of the patient burdens and other complications associated with the use of external pumps to administer prostacyclin analogues. With our funding, Medtronic completed the DelIVery clinical trial, in order to study the safety of the Remodulin Implantable System while administering Remodulin. The primary objective was to demonstrate a rate of catheter-related complications below 2.5 per 1,000 patient-days while using the Remodulin Implantable System to deliver Remodulin. In September 2013, Medtronic informed us that this primary objective was met (p<0.0001).

In order to launch the Remodulin Implantable System in the United States, we are pursuing parallel regulatory filings with Medtronic relating to the drug and the device, respectively. In December 2014, Medtronic submitted a premarket approval application (PMA) seeking FDA approval for the catheter and labeling changes for the SynchroMed II pump. Medtronic is entirely responsible for responding to any FDA requests for additional information concerning the use of the Remodulin Implantable System with Remodulin. In March 2015, the FDA requested that Medtronic amend its PMA to reflect an amendment to the SynchroMed II PMA separately submitted by Medtronic's neuromodulation business unit. Medtronic submitted an amendment to its PMA, which was accepted for review by FDA in January 2016, with FDA action expected in 2016.

## Table of Contents

In January 2015, we submitted a supplemental NDA with new labeling requesting FDA approval to allow the use of Remodulin with the Remodulin Implantable System. The FDA issued a refuse-to-file letter in March 2015, which meant we would need to address FDA comments and resubmit our filing. The FDA also indicated that our submission will be treated as a new NDA. We resubmitted our filing as a new NDA in December 2015, and we expect a ten-month review period (October 2016).

In April 2015, the FDA filed a consent decree requiring Medtronic to stop manufacturing, designing and distributing SynchroMed II implantable infusion pump systems, except in limited circumstances, citing violations of the quality system regulation for medical devices. The consent decree will remain in effect until the FDA has determined that Medtronic has met all the provisions listed in the consent decree. It is unclear how this consent decree will impact our program to develop and commercialize the Remodulin Implantable System, and we anticipate further insight regarding the potential impact on our program in 2016 when the FDA responds to Medtronic's PMA filing.

Subcutaneous Remodulin Administered via Pre-Filled, Semi-Disposable Pump

In December 2014, we entered into an exclusive agreement with DEKA Research & Development Corp. (DEKA) to develop a pre-filled, semi-disposable pump system for subcutaneous delivery of Remodulin. Under the terms of the agreement, we will fund the development costs related to the semi-disposable pump system and will pay product fees and a single-digit royalty to DEKA based on commercial sales of the system and the Remodulin sold for use with the system. Currently, we are undertaking engineering, design and development work to optimize the DEKA pump to deliver Remodulin in pre-filled reservoirs, and intend to conduct human factor studies in healthy volunteers before submitting an application to the FDA to approve the pre-filled DEKA pump. We do not anticipate that the FDA will require us to conduct clinical trials in patients. Our goal is to be in a position to receive FDA approval for this delivery system by the end of 2018.

## Tyvaso

We are developing further enhancements intended to make the Tyvaso Inhalation System easier to use. In addition, we are studying Tyvaso in combination with esuberaprost, as discussed below, and we are planning a phase II study of Tyvaso in patients with pulmonary hypertension associated with idiopathic pulmonary fibrosis.

# Orenitram

In December 2013, the FDA approved Orenitram for the treatment of PAH in WHO Group 1 patients to improve exercise capacity. The primary study that supported efficacy of Orenitram was a 12-week monotherapy study (FREEDOM-M) in which PAH patients were not on any approved background therapy.

We believe that in order for Orenitram to reach its full commercial potential, we need to complete further studies to support an amendment to Orenitram's label to indicate that Orenitram delays morbidity and mortality (also known as "time to clinical worsening") in patients who are on an approved oral background therapy. As such, we are enrolling up to 610 patients in a phase IV clinical trial called FREEDOM-EV, which began in 2012. FREEDOM-EV is a placebo-controlled study of patients who enter the study on an approved background therapy, and one of the two primary endpoints of the study is the time to clinical worsening.

We expect to seek approval of Orenitram in Europe upon completion of the FREEDOM-EV study. In 2005, the EMA announced that Orenitram had been designated an orphan medicinal product for the treatment of PAH. Our request for orphan drug designation for Orenitram for PAH is pending before the FDA.

## Table of Contents

# Esuberaprost

We have been studying various formulations of beraprost since 2000, under a license agreement with Toray Industries, Inc. (Toray). In July 2012, we completed a phase I safety trial of esuberaprost, a reformulated, single-isomer version of beraprost, and the data suggested that dosing esuberaprost four times a day was safe. We believe that esuberaprost and treprostinil have differing prostacyclin receptor-binding profiles and thus could provide benefits to certain groups of patients with differing sets of safety and efficacy profiles. We also believe that inhaled treprostinil and esuberaprost have complimentary pharmacokinetic and pharmacodynamic profiles, which indicate that they should provide greater efficacy in combination. As a result, in 2013 we began enrolling a phase III study called BEAT (*BE*raprost 314d Add-on to *Tyvaso*) to evaluate the clinical benefit and safety of esuberaprost in combination with Tyvaso for patients with PAH who show signs of deterioration on inhaled treprostinil or have a less than optimal response to inhaled treprostinil treatment. We intend to enroll 240 patients in the study, which will have a primary endpoint of time to clinical worsening.

# Cancer-Related Projects

#### Unituxin

In March 2015, the FDA approved our Biologics License Application (BLA) for Unituxin, in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF), interleukin-2 (IL-2), and 13-cis-retinoic acid (RA), for the treatment of pediatric patients with high-risk neuroblastoma who achieve at least a partial response to prior first-line multiagent, multimodality therapy. We commenced U.S. sales of Unituxin in the third quarter of 2015. We received European Commission approval during the third quarter of 2015, and plan to commence commercial sales in individual European countries following pricing and reimbursement approvals on a country-by-country basis.

We previously received orphan drug designation for Unituxin from both the FDA and the EMA. Orphan designation, coupled with FDA approval of our BLA, confers an exclusivity period through March 2022, during which the FDA may not approve any application to market the same drug for the same indication, except in limited circumstances. In lieu of a royalty payment to the NCI, we have an ongoing obligation to provide the NCI with Unituxin for its studies free of charge.

Under our BLA approval for Unituxin, the FDA has imposed certain post-marketing requirements and post-marketing commitments on us. We are conducting additional clinical and non-clinical studies to satisfy these requirements and commitments. While we believe we will be able to complete these studies, any failure to satisfy these requirements or commitments could result in penalties, including fines or withdrawal of Unituxin from the market, unless we are able to demonstrate good cause for the failure.

# **Organ Transplantation**

We are engaged in research and development into a variety of technologies designed to increase the supply of transplantable organs and tissues and improve outcomes for transplant recipients. These programs include preclinical research and development of alternative tissue sources through tissue and organ xenotransplantation, as well as regenerative medicine to create engineered organs and organ tissues. Our xenotransplantation efforts are supported in part by a multi-year research and development collaboration with Synthetic Genomics Inc. (SGI), where SGI will develop engineered primary pig cells with modified genomes for use in our xenotransplantation program.

In May 2014 and September 2015, we also completed two separate \$50.0 million investments in the preferred stock of SGI for a total investment, as of December 31, 2015, of \$100.0 million.

We are also conducting a phase II clinical trial in the United States to study the use of ex-vivo lung perfusion technology originally developed in Canada (where it is already used commercially) to

## **Table of Contents**

provide extended preservation and assessment of donated lungs that are initially rejected for transplantation.

In 2014, we completed the construction of a laboratory facility in Silver Spring, Maryland devoted to performing ex-vivo lung perfusion on a fee-for-service basis. In June 2015, we entered into a collaboration agreement with the Mayo Clinic in Jacksonville, Florida (Mayo) to build and operate a second such facility. We are responsible for nearly all costs associated with the construction of the facility on Mayo's campus, as well as the ongoing operating expenses for the facility. We expect to commence construction of the facility during the first quarter of 2016 and complete construction in late 2017.

## **Future Prospects**

The extent of our future success is dependent on, among other things, how well we achieve the following objectives: (1) in the near term, continued sales growth of our current commercial products (including, in particular, Orenitram) by increasing our market share and launching enhancements designed to improve patient care, such as new delivery systems for Remodulin; (2) in the medium term, augmenting our near-term product growth through: (a) the successful launch of Orenitram for use in combination with other oral therapies following positive FREEDOM-EV results, and (b) the launch of esuberaprost in combination with Tyvaso following positive results of the BEAT study; and (3) in the long term, supplementing our oral, inhaled and infused PAH therapy revenues by introducing transplantable cells, tissues and organs that may prove effective in treating PAH and other end-stage diseases.

Our ability to achieve these objectives and sustain our growth and profitability will depend on many factors, including among others: (1) the timing and outcome of preclinical research, clinical trials and regulatory approvals for products we develop; (2) the timing of and the degree of success related to the commercial launch of new products; (3) the demand for our products; (4) the price of our products and the reimbursement of our products by public and private health insurance organizations; (5) the competition we face within our industry; (6) our ability to effectively manage our business in an increasingly complex legal and regulatory environment; (7) our ability to defend against generic competition and challenges to our patents, including the ongoing challenges to our Remodulin, Tyvaso and Orenitram patents and the expected launch of generic versions of Remodulin in the United States in June 2018 and December 2018 by Sandoz and Teva, respectively; and (8) the risks identified in *Item 1A Risk Factors*, included in this Annual Report on Form 10-K.

We will need to construct additional facilities to support the development and commercialization of our products and services. The design and construction of the additional facilities will need to comply with stringent regulatory requirements, some of which have not yet been developed or adopted by the relevant government agencies. The extent to which we fully develop any of these facilities will depend on the progress of our preclinical and clinical development in various earlier stage programs.

We operate in a highly competitive market in which a small number of pharmaceutical companies control a majority of available PAH therapies. These pharmaceutical companies are well established in the market and possess greater financial, technical and marketing resources than we do. In addition, there are a number of investigational products in late-stage development that, if approved, may erode the market share of our existing commercial therapies and make market acceptance more difficult to achieve for any therapies we attempt to market in the future.

# **Financial Position**

Cash and cash equivalents and marketable investments (both current and long-term) at December 31, 2015 and December 31, 2014 were \$991.8 million and \$818.2 million, respectively. The increase of \$173.6 million in unrestricted cash and cash equivalents and marketable securities resulted

## Table of Contents

primarily from \$382.8 million of cash generated from operations and a \$350.0 million cash inflow from investing activities related to the sale of the Rare Pediatric Priority Review Voucher (PPRV) that we received from the FDA in connection with the approval of Unituxin. These increases were partially offset by the use of \$394.5 million to repurchase shares of our common stock and the use of \$133.2 million to settle early conversions of our Convertible Notes. Cash equivalents and marketable investments include long-term marketable investments of \$38.0 million and \$122.7 million at December 31, 2015 and December 31, 2014, respectively. The \$84.7 million decrease in long-term marketable investments was due to the funding requirements for our share repurchase program and settlements of early conversions of our Convertible Notes.

Accounts receivable at December 31, 2015 and December 31, 2014 were \$192.8 million and \$162.3 million, respectively. The increase of \$30.5 million reflected an approximately 14 percent increase in net product sales during the year ended December 31, 2015, compared to the year ended December 31, 2014, and the timing of invoicing and cash collections.

Other assets at December 31, 2015 and December 31, 2014 were \$154.3 million and \$97.9 million, respectively. The increase of \$56.3 million was primarily due to our \$50.0 million investment in SGI.

Convertible notes at December 31, 2015 and December 31, 2014 were \$5.4 million and \$126.4 million, respectively. The decrease of \$121.0 million was due to early conversions of \$133.2 million of principal of our Convertible Notes during the year ended December 31, 2015, net of amortization of \$12.1 million for the unamortized discount of which \$9.1 million was related to the early conversions of our Convertible Notes. Refer to Note 8 *Debt Convertible Notes Due 2016* to the consolidated financial statements contained in this Annual Report on Form 10-K for details.

Other liabilities at December 31, 2015 and December 31, 2014 were \$144.0 million and \$114.5 million, respectively. The increase of \$29.4 million was due primarily to an increase of \$39.0 million in the liability attributed to our outstanding STAP awards during 2015 as a result of a higher stock price at December 31, 2015 as compared to December 31, 2014, partially offset by the aggregation of individually immaterial items.

Additional paid-in capital at December 31, 2015 and December 31, 2014 was \$1,790.6 million and \$1,376.1 million, respectively. The increase of \$414.5 million primarily consisted of \$76.7 million in proceeds from stock option exercises and related tax benefits and \$324.7 million related to the common stock issued in connection with the early conversion of \$133.2 million of principal of our Convertible Notes based on the value of the closing price of our common stock on the date the shares were issued. Refer to Note 11 *Stockholders' Equity Incentive Plan* and Note 8 *Debt Convertible Notes Due 2016* to the consolidated financial statements contained in this Annual Report on Form 10-K for further details.

Treasury stock at December 31, 2015 and December 31, 2014 was \$1,902.1 million and \$1,185.8 million, respectively. The increase of \$716.3 million primarily consisted of: (1) \$394.5 million in expenditures to repurchase approximately 2.4 million shares of our common stock; and (2) \$321.8 million reflecting the value of approximately 2.0 million shares we received under our note hedge in connection with the early conversion of \$133.2 million of principal of our Convertible Notes based on the closing price of our common stock on the date the shares were received. Refer to Note 11 *Stockholders' Equity Share Repurchases* and Note 8 *Debt Convertible Notes Due 2016* to the consolidated financial statements contained in this Annual Report on Form 10-K for further details.

# Table of Contents

# **Results of Operations**

# Years ended December 31, 2015 and 2014

Revenues

The following table presents the components of total revenues (dollars in thousands):

	mber 31,	Percentage			
		2015		2014	Change
Net product sales:					
Remodulin	\$	572,795	\$	553,728	3.4%
Tyvaso		470,069		463,067	1.5%
Adcirca		278,829		221,471	25.9%
Orenitram		118,434		41,267	187.0%
Unituxin		20,443			$NM_{(1)}$
Other		5,191		8,986	(42.2)%
Total revenues	\$	1,465,761	\$	1,288,519	13.8%

(1) Calculation is not meaningful.

Revenues for the year ended December 31, 2015 increased by \$177.2 million compared to the same period in 2014. The growth in revenues primarily resulted from: (1) a \$77.2 million increase in Orenitram net product sales due to an increase in the number of patients being treated with Orenitram, which we launched in the second quarter of 2014; (2) a \$57.4 million increase in Adcirca net product sales due to price increases, which were determined by Lilly, and to a lesser extent by an increase in the number of Adcirca bottles sold; and (3) \$20.4 million in net product sales of Unituxin, which we launched in the third quarter of 2015.

For the years ended December 31, 2015 and 2014, approximately 72 percent and 74 percent, respectively, of total revenues were derived from net product sales of Remodulin, Tyvaso and Orenitram to our U.S.-based specialty pharmaceutical distributors. Remaining revenues were derived primarily from net product sales of Adcirca and Unituxin and net product sales of Remodulin to our international distributors.

We recognize revenues net of: (1) estimated rebates; (2) prompt pay discounts; (3) allowances for sales returns; and (4) distributor fees. These are referred to as gross-to-net deductions and are based on historical experiences and contractual and statutory requirements. The tables below include a reconciliation of the accounts associated with these deductions (in thousands):

	Year Ended December 31, 2015									
		Rebates		ompt Pay iscounts		wance for es Returns	D	istributor Fees		Total
Balance, January 1, 2015	\$	31,616	\$	3,285	\$	4,028	\$	557	\$	39,486
Provisions attributed to sales in:										
Current period		171,653		33,508		2,640		9,830		217,631
Prior periods		44				339		(255)		128
Payments or credits attributed to										
sales in:										
Current period		(123,855)		(29,645)				(7,253)		(160,753)
Prior periods		(34,840)		(3,245)		(1,724)		(286)		(40,095)
-										
Balance, December 31, 2015	\$	44,618	\$	3,903	\$	5,283	\$	2,593	\$	56,397

# Table of Contents

	Year Ended December 31, 2014									
		Pro		npt Pay	Allowance for			Distributor		
		Rebates	Dis	counts	Sal	es Returns		Fees		Total
Balance, January 1, 2014	\$	22,475	\$	2,500	\$	2,862	\$	1,092	\$	28,929
Provisions attributed to sales in:										
Current period		116,813		27,096		1,671		7,854		153,434
Prior periods		6,622				429		278		7,329
Payments or credits attributed to										
sales in:										
Current period		(85,833)		(23,998)				(7,139)		(116,970)
Prior periods		(28,461)		(2,313)		(934)		(1,528)		(33,236)
Balance, December 31, 2014	\$	31,616	\$	3,285	\$	4.028	\$	557	\$	39,486

# Research and Development Expense

The table below summarizes research and development expense by major project and non-project components (dollars in thousands):

	Year l Decem	 	Percentage
	2015	2014	Change
Project and non-project:			
Cardiopulmonary	\$ 130,097	\$ 131,843	(1.3)%
Share-based compensation expense	87,713	72,714	20.6%
Other	27,288	37,992	(28.2)%
Total research and development expense	\$ 245,098	\$ 242,549	1.1%

*Share-based compensation.* The increase in share-based compensation of \$15.0 million for the year ended December 31, 2015, as compared to the same period in 2014, corresponded to a 21 percent appreciation in the price of our common stock during the year ended December 31, 2015, compared to a 15 percent appreciation in the price of our common stock price during the year ended December 31, 2014.

*Other.* The decrease in other research and development expenses of \$10.7 million for the year ended December 31, 2015, as compared to the same period in 2014, was primarily attributable to a \$6.4 million decrease in expenditures for our development of Unituxin, which was approved by the FDA in March of 2015, and a \$3.9 million decrease in research and development expenditures not allocated to specific projects.

Selling, General and Administrative Expense

The table below summarizes selling, general and administrative expense by major categories (dollars in thousands):

	Year I Decem	 	Percentage
	2015	2014	Change
Category:			
General and administrative	\$ 174,570	\$ 186,312	(6.3)%
Sales and marketing	94,297	82,000	15.0%
Share-based compensation expense	183,745	112,975	62.6%
Total selling, general and administrative expense	\$ 452,612	\$ 381,287	18.7%

## Table of Contents

General and administrative. The decrease in general and administrative expenses of \$11.7 million for the year ended December 31, 2015, as compared to the same period in 2014, was attributable to: (1) a \$12.7 million decrease due to timing of grants to non-affiliated, non-profit organizations that provide financial assistance to patients with PAH; and (2) a \$9.4 million decrease in legal expenses resulting from the April 2015 closure of an investigation by the Office of Inspector General of the Department of Health and Human Services related to our marketing practices; partially offset by (3) a \$10.0 million increase in salaries and other compensation-related expenses driven by the general expansion of our business.

Sales and marketing. The increase in sales and marketing expenses of \$12.3 million for the year ended December 31, 2015. as compared to the same period in 2014, was driven by: (1) an \$8.6 million increase in marketing activities for all of our commercial products, primarily for our most recently approved PAH product, Orenitram, and our first oncology product, Unituxin; and (2) a \$3.7 million increase in salaries and other compensation-related expenses driven by the expansion of our personnel in connection with the growth of our commercial product portfolio.

*Share-based compensation.* The increase in share-based compensation of \$70.8 million for the year ended December 31, 2015, as compared to the same period in 2014, corresponded to a 21 percent appreciation in the price of our common stock during the year ended December 31, 2015, compared to the approximately 15 percent appreciation in our stock price during the same period in 2014.

## Cost of Product Sales

The table below summarizes cost of product sales by major category (dollars in thousands):

	Ye	Percentage		
		2015	Change	
Category:				
Cost of product sales	\$	60,240	\$ 121,518	(50.4)%
Share-based compensation expense		8,796	4,365	101.5%
Total cost of product sales	\$	69,036	\$ 125,883	(45.2)%

Cost of Product Sales. The decrease in cost of product sales of \$61.3 million for the year ended December 31, 2015 as compared to the same period in 2014, resulted primarily from the expiration of our royalty obligation to Glaxo in October 2014. During the twelve months ended December 31, 2014, we incurred \$72.5 million in royalty expense related to this obligation. This decrease was partially offset by: (1) an increase in the cost of product sales of \$5.6 million and \$3.0 million relating to Orenitram and Adcirca, respectively due to increased sales of these products in 2015; and (2) \$3.2 million in cost of product sales relating to Unituxin which was commercially launched during the third quarter of 2015.

Share-based compensation. The increase in share-based compensation of \$4.4 million for the year ended December 31, 2015 as compared to the same period in 2014, corresponded to a 21 percent appreciation in the price of our common stock during the year ended December 31, 2015, compared to the approximately 15 percent appreciation in our stock price during the same period in 2014.

## Gain on Sale of Intangible Asset

In September 2015, we sold the PPRV we received from the FDA in connection with the approval of Unituxin for \$350.0 million in cash. The proceeds from the sale of the PPRV were recognized as a gain on the sale of an intangible asset, as the PPRV did not have a carrying value on our consolidated balance sheet at the time of sale.

# Table of Contents

Income Tax Expense

The provision for income taxes was \$392.8 million for the year ended December 31, 2015 compared to \$185.1 million for the same period in 2014. The increase in the provision for income taxes corresponded to the increase in income before income taxes. For the years ended December 31, 2015 and December 31, 2014, the effective tax rates were approximately 38 percent and 35 percent, respectively. For additional details refer to Note 13 *Income Taxes* to the consolidated financial statements contained in this Annual Report on 10-K.

## Years ended December 31, 2014 and 2013

## Revenues

The following table presents the components of total revenues (dollars in thousands):

	Year Ended	Percentage		
	2014	14 2013		Change
Net product sales:				
Remodulin	\$ 553,728	\$	491,179	12.7%
Tyvaso	463,067		438,793	5.5%
Adcirca	221,471		176,972	25.1%
Orenitram	41,267			$NM_{(1)}$
Other	8,986		10,040	(10.5)%
Total revenues	\$ 1.288.519	\$	1.116.984	15.4%

(1) Calculation is not meaningful.

Revenues for the year ended December 31, 2014 increased by \$171.5 million compared to the same period in 2013. The growth in revenues primarily resulted from: (1) a \$62.5 million increase in Remodulin net product sales due to an increase in the number of patients being treated with Remodulin; (2) a \$44.5 million increase in Adcirca net product sales due to price increases, which were determined by Lilly, and to a lesser extent by an increase in the number of Adcirca bottles sold; (3) a \$24.3 million increase in Tyvaso net product sales mostly due to a price increase on January 1, 2014; and (4) \$41.3 million in net product sales of Orenitram, which we launched during the second quarter of 2014.

For the years ended December 31, 2014 and 2013, approximately 74 percent and 76 percent, respectively, of total revenues were derived from net product sales of Remodulin, Tyvaso and Orenitram to our U.S.-based specialty pharmaceutical distributors. Remaining revenues were derived primarily from net product sales of Adcirca and net product sales of Remodulin and Tyvaso to our international distributors.

# Table of Contents

The table below includes a reconciliation of the accounts associated with estimated rebates, prompt-pay discounts, allowances for sales returns and distributor fees (in thousands):

	Year Ended December 31, 2014										
	Prompt P			mpt Pay	All	owance for	D	istributor			
	]	Rebates	Di	scounts	Sal	les Returns		Fees		Total	
Balance, January 1, 2014	\$	22,475	\$	2,500	\$	2,862	\$	1,092	\$	28,929	
Provisions attributed to sales in:											
Current period		116,813		27,096		1,671		7,854		153,434	
Prior periods		6,622				429		278		7,329	
Payments or credits attributed to											
sales in:											
Current period		(85,833)		(23,998)				(7,139)		(116,970)	
Prior periods		(28,461)		(2,313)		(934)		(1,528)		(33,236)	
Balance, December 31, 2014	\$	31.616	\$	3,285	\$	4.028	\$	557	\$	39,486	

	Year Ended December 31, 2013									
			Prompt Pay		Allowance for		Distributor			
	Rebates		Discounts		Sales Returns		Fees			Total
Balance, January 1, 2013	\$	15,207	\$	2,115	\$	3,350	\$	1,281	\$	21,953
Provisions attributed to sales in:										
Current period		81,938		24,154		1,254		7,008		114,354
Prior periods		997				(1,530)		3		(530)
Payments or credits attributed to sales										
in:										
Current period		(59,225)		(21,654)				(5,916)		(86,795)
Prior periods		(16,442)		(2,115)		(212)		(1,284)		(20,053)
Balance, December 31, 2013	\$	22,475	\$	2,500	\$	2,862	\$	1,092	\$	28,929

# Research and Development Expense

The table below summarizes research and development expense by major project and non-project components (dollars in thousands):

	Year l Decem	Percentage Change		
	2014			
Project and non-project:				
Cardiopulmonary	\$ 131,843	\$ 116,137	13.5%	
Share-based compensation expense	72,714	134,706	(46.0)%	
Other	37,992	48,505	(21.7)%	
Total research and development expense	\$ 242,549	\$ 299,348	(19.0)%	

*Cardiopulmonary.* The increase in cardiopulmonary program expenses of \$15.7 million for the year ended December 31, 2014, compared to the year ended December 31, 2013, resulted from a \$20.1 million increase in expenses related to our esuberaprost program, partially offset by a \$7.9 million decrease in expenses related to our self-injectable treprostinil program, which we terminated during 2014.

Share-based compensation. The decrease in share-based compensation of \$62.0 million for the year ended December 31, 2014, compared to the year ended December 31, 2013, resulted from the approximately 15 percent appreciation in the price of our common stock during the year ended

## **Table of Contents**

December 31, 2014, compared to the approximately 112 percent appreciation in the price of our common stock price during the year ended December 31, 2013.

*Other.* The decrease in other research and development expenses of \$10.5 million for the year ended December 31, 2014, compared to the year ended December 31, 2013, was attributable to a \$7.5 million decrease in research and development expenditures not allocated to specific projects and a \$1.6 million decrease in expenditures for our development of Unituxin.

Selling, General and Administrative Expense

The table below summarizes selling, general and administrative expense by major category (dollars in thousands):

		Year l Decem	Percentage			
	2014			2013	Change	
Category:						
General and administrative	\$	186,312	\$	140,235	32.9%	
Sales and marketing		82,000		73,871	11.0%	
Share-based compensation expense		112,975		179,904	(37.2)%	
Total selling, general and administrative expense	\$	381,287	\$	394,010	(3.2)%	

General and administrative. The increase in general and administrative expenses of \$46.1 million for the year ended December 31, 2014, compared to the year ended December 31, 2013, was driven by the following: (1) an \$18.2 million increase in consulting and professional fees primarily driven by our patent litigation and our response to a subpoena issued by the OIG relating to our marketing practices; (2) an \$8.7 million increase in grants to non-affiliated, non-profit organizations that provide financial assistance to patients with PAH; and (3) \$5.4 million and \$7.5 million increases in operating expenses and salaries and other compensation-related expenses, respectively, associated with the general expansion of our business and the reclassification of certain staff from research and development to a general and administrative classification.

*Sales and marketing.* The increase in sales and marketing expenses of \$8.1 million reflects the following increases: (1) \$5.3 million increase in salaries and other compensation-related expenses as we expanded our sales personnel during 2014; and (2) a \$2.8 million increase in marketing activities.

Share-based compensation. The decrease in share-based compensation of \$66.9 million for the year ended December 31, 2014, compared to the year ended December 31, 2013, corresponded to the approximately 15 percent appreciation in the price of our common stock during the year ended December 31, 2014, compared to the approximately 112 percent appreciation in our stock price during the year ended December 31, 2013.

## Table of Contents

# Cost of Product Sales

The table below summarizes cost of product sales by major category (dollars in thousands):

	Y	ear Ended	Percentage		
	2014		2013	Change	
Category:					
Cost of product sales	\$	121,518	\$ 124,952	(2.7)%	
Share-based compensation (benefit) expense		4,365	6,175	(29.3)%	
Total cost of product sales	\$	125,883	\$ 131,127	(4.0)%	

Cost of Product Sales. Cost of product sales decreased by \$3.4 million for the year ended December 31, 2014, compared to the year ended December 31, 2013. The decrease resulted primarily from the expiration of our royalty obligation to Glaxo in October 2014.

Share-based compensation. The decrease in share-based compensation of \$1.8 million for the year ended December 31, 2014, compared to the year ended December 31, 2013, corresponded to the approximately 15 percent appreciation in the price of our common stock during the year ended December 31, 2014, compared to the approximately 112 percent appreciation in our stock price during the year ended December 31, 2013.

# Income Tax Expense

The provision for income taxes was \$185.1 million for the year ended December 31, 2014 compared to \$104.3 million for the year ended December 31, 2013. The increase in the provision for income taxes corresponded to the increase in income before income taxes. For the years ended December 31, 2014 and December 31, 2013, the effective tax rates were approximately 35 percent and 37 percent, respectively. For additional details refer to Note 13 *Income Taxes* to the consolidated financial statements contained in this Annual Report on 10-K.

### **Liquidity and Capital Resources**

We have funded our operations principally through sales of our commercial products and, from time-to-time, third-party financing arrangements. We believe that our current liquidity is sufficient to fund ongoing operations and future business plans as we expect demand for our commercial products to continue to grow. Furthermore, our customer base remains stable and we believe it presents minimal credit risk. However, any projections of future cash flows are inherently subject to uncertainty and we may seek other forms of financing. In January 2016, we entered into a credit agreement providing a five-year, unsecured, revolving line of credit of up to \$1.0 billion. See *Unsecured Revolving Credit Facility* below for further details.

# Cash Flows

# 2015 Compared to 2014

Operating Activities

Our operating assets and liabilities consist primarily of accounts receivable, inventories, accounts payable and accrued expenses, which include share-based compensation arrangements. During the periods presented in the accompanying financial statements, the combination of revenue growth and profitable operations has resulted in positive cash flows provided by operations.

# Table of Contents

Net cash provided by operating activities was \$382.8 million for the year ended December 31, 2015, compared to \$355.3 million for the year ended December 31, 2014. The \$27.5 million increase in cash flows from operations was primarily due to the following year-over-year changes:

(1) Increases in cash provided by operating activities:

\$177.2 million increase in revenues during the year ended December 31, 2015 compared to the same period in 2014, which resulted in higher cash collections;

\$23.7 million increase in cash flows due to an increase in accounts payable and accrued expenses at December 31, 2015 compared to the prior year;

\$14.2 million increase in cash flows due to a decrease in payments for inventory during the year ended December 31, 2015 due to increased sales; and

\$14.9 million increase in cash flows due to the aggregation of individually immaterial changes to operating assets and liabilities.

(2) Decreases in cash provided by operating activities:

\$104.7 million increase in cash paid to settle STAP awards. Cash paid to settle STAP awards exercised during the years ended December 31, 2015 and December 31, 2014 was \$248.8 million and \$144.1 million, respectively; and

\$97.8 million increase in cash paid for income taxes. Cash paid for income taxes during the years ended December 31, 2015 and December 31, 2014 was \$293.3 million and \$195.6 million, respectively.

# Investing

Net cash provided by investing activities was \$503.6 million for the year ended December 31, 2015, compared to \$338.5 million for the year ended December 31, 2014. The \$165.1 million increase in net cash provided by investing activities reflects \$350.0 million of cash from the sale of our PPRV in September 2015, partially offset by a decrease of cash provided from the net maturities of held-to-maturity investments of \$173.3 million. Cash provided from net maturities of held-to-maturity investments during the year ended December 31, 2015 was \$257.6 million, compared to \$430.9 million of cash provided from the net maturities of held-to-maturity investments during the same period in 2014. Due to the funding requirements for our share repurchase program and settlements of early conversions of our Convertible Notes, we decreased the amount of cash we were reinvesting in held-to-maturity investments.

# Financing

Net cash used in financing activities was \$446.9 million for the year ended December 31, 2015, compared to \$576.5 million for the year ended December 31, 2014. The \$129.6 million decrease reflects a decrease of \$88.6 million in repurchases of our common stock, due to the completion of our repurchase program in August 2015, and a decrease of \$44.7 million in principal payments of debt during the year ended December 31, 2015 compared to the year ended December 31, 2014. as a result of less early conversion requests on our Convertible Notes.

# Table of Contents

# 2014 Compared to 2013

**Operating** 

Net cash provided by operating activities was \$355.3 million for the year ended December 31, 2014, compared to \$425.3 million for the year ended December 31, 2013. The \$70.0 million decrease in cash flows from operations was primarily due to the following year-over-year changes:

(1) Increase in cash provided by operating activities:

\$171.5 million increase in revenues during the year ended December 31, 2014 compared to the same period in 2013, which resulted in higher cash collections.

(2) Decreases in cash provided by operating activities:

\$88.2 million increase in cash paid to settle STAP awards. Cash paid to settle STAP awards exercised during the years ended December 31, 2014 and December 31, 2013 was \$144.1 million and \$55.9 million, respectively;

\$53.4 million increase in cash paid for income taxes. Cash paid for income taxes during the years ended December 31, 2014 and December 31, 2013 was \$195.6 million and \$142.1 million, respectively;

\$25.7 million decrease in cash flow due to the timing of cash collections in accounts receivable;

\$14.3 million decrease in cash flow due to an increase in cash payments of our accounts payable resulting in a lower accounts payable and accrued expenses balance at December 31, 2014 compared with the prior year; and

\$59.9 million decrease in cash flows due to the aggregation of individually immaterial changes to operating assets and liabilities.

# Investing

Net cash provided by investing activities was \$338.5 million for the year ended December 31, 2014, compared to net cash used in investing activities of \$295.0 million for the year ended December 31, 2013. The increase of \$633.4 million in cash provided by investing activities reflects \$430.9 million of cash provided from the net maturities of held-to-maturity investments during the year ended December 31, 2014, compared to \$232.3 million in net purchases of held-to-maturity investments during the same period in 2013. Due to the funding requirements in 2014 for our ongoing share repurchase programs and settlements of early conversions of our Convertible Notes, we did not reinvest the proceeds from our maturing investments. This increase in cash from maturing investments was partially offset by a \$15.5 million increase in capital expenditures relating primarily to the completion of facilities used in our lung transplantation programs.

## Financing

Net cash used in financing activities was \$576.5 million for the year ended December 31, 2014, compared to \$5.1 million for the year ended December 31, 2013. The \$571.4 million increase in cash used in financing activities reflects an increase of \$440.6 million in repurchases of our common stock and an increase of \$176.5 million in principal payments of debt, partially offset by a \$45.1 million increase in proceeds and tax benefits from the exercise of stock options during the year ended December 31, 2014, compared to the year ended December 31, 2013.

## Table of Contents

# Unsecured Revolving Credit Facility

In January 2016, we entered into a Credit Agreement (the 2016 Credit Agreement) with Wells Fargo Bank, National Association (Wells Fargo), as administrative agent and a swingline lender, and various other lender parties, providing for an unsecured revolving credit facility of up to \$1.0 billion (the Revolving Facility), which is available to refinance certain of our existing indebtedness and/or for working capital and other general corporate purposes. The Revolving Facility will mature five years after the closing date of the 2016 Credit Agreement, subject to the lenders' ability to extend the maturity date by one year if we request such an extension in accordance with the terms of the 2016 Credit Agreement.

At our option, amounts borrowed under the Revolving Facility will bear interest at either the LIBOR rate or a fluctuating base rate, in each case, plus an applicable margin determined on a quarterly basis based on our consolidated ratio of total indebtedness to EBITDA (as calculated in accordance with the 2016 Credit Agreement).

The 2016 Credit Agreement contains customary events of default and customary affirmative and negative covenants. As of January 29, 2016, we were in compliance with such covenants and we had not drawn any amounts on the Revolving Facility. In addition, Lung Biotechnology PBC is our only subsidiary that guarantees our obligations under the 2016 Credit Agreement though, from time to time, one or more of our other subsidiaries may be required to guarantee such obligations.

# Secured Line of Credit

In September 2013, we entered into a one-year Credit Agreement (the 2013 Credit Agreement) with Wells Fargo for a \$75.0 million revolving loan facility. In July 2015, we amended the Credit Agreement solely to extend its maturity to September 30, 2017. We used this facility for general corporate purposes. At our option, amounts borrowed under the Credit Agreement bore interest at either the one-month LIBOR rate plus a 0.50 percent margin, or a fluctuating base rate excluding any margin. In addition, we were subject to a monthly commitment fee at a rate of 0.06 percent per annum based on the average daily unused balance of the facility. Amounts borrowed under the Credit Agreement were secured by certain of our marketable investments. As of December 31, 2015, we had no outstanding balance on the line of credit. In January 2016, we terminated and repaid in full all obligations under the 2013 Credit Agreement when we entered into the 2016 Credit Agreement.

#### Convertible Senior Notes

In October 2011, we issued the Convertible Notes with an aggregate principal value of \$250.0 million. Please see Note 8 *Debt*, to our consolidated financial statements contained elsewhere in this Annual Report on Form 10-K, for a description of the Convertible Notes. As of December 31, 2015, the outstanding principal balance of our Convertible Notes was \$5.6 million, which is due on September 15, 2016.

# Mortgage Financing

In December 2010, we entered into a Credit Agreement with Wells Fargo and Bank of America, N.A., pursuant to which we obtained a \$70.0 million mortgage loan (the 2010 Credit Agreement). The 2010 Credit Agreement matured in December 2014 and we repaid in full the outstanding \$66.5 million principal balance.

# Share Tracking Award Plans

Awards granted under our STAP entitle participants to receive in cash an amount equal to the appreciation in our common stock, which is calculated as the increase in the closing price of our

## Table of Contents

common stock between the grant date and the exercise date. Cash requirements associated with the exercise of awards will likely be significant, with the actual requirements dependent on future stock price fluctuation and STAP award exercise activity. At December 31, 2015, the aggregate liability associated with vested STAP awards was \$194.4 million, and the aggregate liability associated with all STAP awards was \$354.8 million. We review the potential future cash requirements of the STAP program at least annually. Based on our review, we believe we currently have sufficient cash and cash equivalents and borrowing capacity to fund any STAP awards that could be exercised during 2016 and beyond. Following the adoption of the 2015 Plan, which is discussed above under *Operating Expenses Share-Based Compensation*, we discontinued the issuance of STAP awards and modified our compensation programs to provide for future awards in the form of stock options instead of STAP awards.

# Share Repurchases

From time to time, our Board of Directors authorizes plans to repurchase shares of our common stock. In June 2014, our Board of Directors authorized the repurchase of up to \$500.0 million of our common stock. This program became effective on August 1, 2014, and remained open for one year. In the aggregate, we repurchased approximately 3.3 million shares of common stock under this program for \$500.0 million.

In October 2015, our Board of Directors authorized a new program for the repurchase of up to \$500.0 million of our common stock in open or privately negotiated transactions, at our discretion. This program is effective from January 1, 2016 to December 31, 2016. During the month ended January 31, 2016, we repurchased approximately 280,000 shares of our common stock at an aggregate cost of \$37.8 million. We currently have sufficient cash and cash equivalents, borrowing capacity and, if needed, marketable investments, to fund additional repurchases of our common stock under this program.

## Toray License Obligations

Pursuant to a March 2007 amendment to our license agreement with Toray, we issued 200,000 shares of our common stock to Toray. Toray has the right to request that we repurchase these shares (which have since split into 400,000 shares) upon 30 days prior written notice at the price of \$27.21 per share. To date, Toray has not notified us that it intends to require us to repurchase these shares. In 2011, we amended our license agreement with Toray to reduce the royalty rates in exchange for a total of \$50.0 million in equal, non-refundable payments to Toray over the five-year period ending in 2015. As of December 31, 2015, we have fulfilled our \$50.0 million royalty obligation to Toray.

# Obligations Under License and Assignment Agreements

We pay Lilly a five percent royalty on net product sales of Adcirca and we pay a single-digit percentage royalty based on net product sales of Orenitram, under our license agreement with Supernus Pharmaceuticals Inc. We have entered into other license rights arrangements under which we are required to make milestone payments upon the achievement of certain developmental and commercialization objectives and royalty payments upon the commercialization of related licensed technology.

## **Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements within the meaning of Item 303(a)(4) of Regulation S-K.

#### Table of Contents

### **Contractual Obligations**

At December 31, 2015, we had the following contractual obligations (in thousands):

	Payments Due by Period Less than More th									
		Total	1	1 year	2	- 3 Years	4	- 5 Years		Iore than 5 Years
Convertible Notes	\$	5,600	\$	5,600	\$		\$		\$	
Mortgage and other loans		3,703		3,495		138		70		
Operating lease obligations		10,534		3,716		6,083		735		
Obligations under the STAP <sup>(1)</sup>		460,450		267,603		191,301		1,546		
Obligations under the SERP <sup>(2)</sup>		71,067		14,651				4,580		51,836
Purchase commitments		15,821		14,717		1,076		28		
Milestone payments under license and acquisition agreements <sup>(3)</sup>		33,021		6,136		8,345		11,470		7,070
Total	\$	600,196	\$	315.918	\$	206.943	\$	18.429	\$	58.906

- (1) Estimated based on the intrinsic value of outstanding STAP awards vested and expected to vest, assuming that unvested awards will be exercised immediately upon vesting. Refer to Note 7 Share Tracking Award Plans to our consolidated financial statements included in this Annual Report on Form 10-K for further details.
- (2)
  Consists of actuarially derived, estimated future payouts of benefits. Refer to Note 14 Employee Benefit Plans Supplemental Executive Retirement Plan to our consolidated financial statements included in this Annual Report on Form 10-K for further details.
- Based on our estimates of the timing and probability of achieving milestones specified under our various license and acquisition agreements. Amount includes \$21.4 million of contingent consideration and future payments that are recorded within other liabilities (current and non-current) on the consolidated balance sheet as of December 31, 2015. All other amounts have not been recorded as of December 31, 2015, because required milestones have not been met. The amounts and timing of future milestone payments may vary depending on when related milestones will be attained, if at all.

### **Summary of Critical Accounting Policies and Estimates**

We prepare our consolidated financial statements in conformity with generally accepted accounting principles in the United States (GAAP). GAAP requires that we make estimates and assumptions that affect the amounts and timing reported in our consolidated financial statements. As we become aware of updated information or new developments, these estimates and assumptions may change and materially impact reported amounts. We consider the following accounting policies to be critical to our consolidated financial statements because they require the use of our judgment and estimates (including those that are forward-looking) in their application.

#### Revenue Recognition

Remodulin, Tyvaso, Orenitram and Unituxin

We market Remodulin, Tyvaso, Orenitram and Unituxin to specialty distributors in the United States and other distributors internationally under materially similar contractual arrangements. Net product sales of Remodulin, Tyvaso, Orenitram and Unituxin are recognized when title and risk of ownership pass to our distributors upon satisfactory delivery to our distributors' facilities i.e., when all of our performance obligations under these distributor arrangements have been satisfied. We record

#### Table of Contents

sales of Remodulin, Tyvaso, Orenitram and Unituxin net of: (1) estimated rebates; (2) prompt payment discounts; (3) service fees we pay to distributors; and (4) an allowance for return rights. Determining sales allowances involves the use of significant estimates and judgment and may involve the use of information from external sources.

We derive our provisions for rebates from an analysis of historical levels of rebates to both state Medicaid agencies and commercial third-party payers by product, relative to sales of each product. In addition, we determine our obligation for prescription drug discounts required for Medicare Part D Orenitram patients within the coverage gap based on estimations of the number of Medicare Part D Orenitram patients and the period that such patients will remain within the coverage gap. In formulating our estimates, we also consider the impact of anticipated changes in product prices, sales trends and changes to government rebate programs, particularly as they relate to eligibility requirements and/or rebate pricing. We analyze rebate data separately for Remodulin, Tyvaso and Orenitram, as these therapies have different routes of administration to treat PAH patients at different stages in the disease continuum and therefore, rebate eligibility and pricing requirements can differ for each therapy.

We estimate prompt pay discounts based on observed payment behavior. Our distributors have routinely taken advantage of these discounts and we expect them to continue to do so.

We pay our distributors for contractual services rendered and accrue for related fees based on contractual rates applied to the estimated units of service provided by distributors for a given financial reporting period.

Our distributors do not possess return rights for Remodulin, Tyvaso and Orenitram; however, the sales terms for Unituxin include return rights that extend throughout the distribution channel. We provide exchange rights for all products in the event that product is damaged during shipment or expires. Exchanges for damaged product are highly infrequent. In the event that Remodulin, Tyvaso, Orenitram or Unituxin has been damaged during shipment and we have been promptly notified as required under our distribution agreements, we do not recognize revenue on that shipment until damaged product has been replaced. Replacement of damaged product generally occurs within several days after notification of the damage. Furthermore, the number of product exchanges due to expiration has been minimal because we sell Remodulin, Tyvaso and Orenitram with a remaining shelf life in excess of one year and our distributors typically carry a thirty- to sixty-day supply of our treprostinil-based products at any given time. In addition, we closely track inventory levels held by our distributors. Except for contractual minimum inventory levels to prevent shortages of treprostinil-based drug supply, we do not require, nor do we provide incentives for our distributors to assume, inventory levels of Remodulin, Tyvaso, Orenitram or Unituxin beyond what would be considered reasonable and customary in the ordinary course of business.

The financial effects of exchange rights for Remodulin, Tyvaso, Orenitram and Unituxin have been immaterial and we expect the volume of exchanges to be consistent with historical levels. Specifically, exchanges of Remodulin, Tyvaso, Orenitram and Unituxin have comprised substantially less than one percent of the volume of the units that we sell. Because historical and anticipated future exchanges of Remodulin, Tyvaso, Orenitram and Unituxin have been and are expected to be immaterial, we do not record a reserve for estimated exchange rights in the period of sale. Lastly, we closely monitor product exchange data for all of these therapies to ensure that our assumptions continue to be reasonable, appropriate and current.

### Adcirca

Addirca is manufactured for us by Eli Lilly and Company (Lilly) and distributed through Lilly's pharmaceutical wholesaler network. Specifically, Lilly handles all of the administrative functions associated with the sale of Addirca on our behalf, including the receipt and processing of customer

#### **Table of Contents**

purchase orders, shipment to customers, and invoicing and collection of customer payments. In addition, the sales terms for Adcirca include return rights that extend throughout the distribution channel. We recognize sales of Adcirca on a gross basis (net of allowances) upon delivery to customers due to the following factors: (1) we are responsible for the acceptability of the product purchased by wholesalers; (2) we bear all inventory risk, as title and risk of loss pass to us at the shipping point from Lilly's manufacturing facility; (3) we assume credit risk if Lilly is unable to collect amounts due from customers; and (4) we assume the risk and cost of a product recall, if required.

We recognize sales of Adcirca net of: (1) estimated government-based and commercial payer rebates; (2) prompt pay discounts; (3) allowances for product returns; and (4) wholesaler fees. We estimate our liability for rebates based on an analysis of historical levels of rebates to both Medicaid and commercial third-party payers and we consider the impact of sales trends, changes in government and commercial rebate programs and anticipated changes in Adcirca's pricing. In addition, for Adcirca patients, we determine our obligation for prescription drug discounts required by Medicare Part D for patients within the coverage gap based on estimations of the number of patients and the period that such patients will remain within the coverage gap. We base our estimates for prompt pay discounts on observed customer payment behavior and expectations regarding the future utilization of such discounts. To date, we have not identified any unusual patterns in the volume of prescriptions relative to sales that would warrant reconsideration of, or adjustment to, the methodology we currently employ to estimate our allowance for returns. Lastly, wholesaler fees are based on contractual percentages of sales to wholesalers.

#### **Share-Based Compensation**

Our share-based awards are classified as either equity (stock options and our employee stock purchase plan) or as liabilities (STAP awards). We recognize related share-based compensation expense based on the fair value of the options granted to purchase stock and on outstanding STAP awards. We estimate the fair value of all share-based awards using the Black-Scholes-Merton valuation model. Valuation models, like the Black-Scholes-Merton model, require the use of subjective assumptions that could materially impact the estimation of fair value and related compensation expense to be recognized. These assumptions include, among others, the expected volatility of our stock price, the expected term of awards and the expected forfeiture rate. Developing these assumptions requires the use of judgment.

### Pension Benefit Obligation

Accounting for our Supplemental Executive Retirement Plan (SERP) requires that we recognize in our consolidated balance sheet a liability equal to the unfunded status of the SERP (the total estimated projected benefit obligation, as we do not fund the SERP) and measure our projected benefit obligation as of the end of our fiscal year. Estimating the SERP obligation involves the use of judgment and estimates. The SERP obligation and related pension expense are derived from actuarial valuations that are developed using a number of assumptions. A key assumption underlying the valuation is the discount rate. The discount rate should be representative of the rate associated with high-quality, fixed-income debt securities. We must consider prevailing economic conditions and outlook, the state of the credit markets and other economic factors when determining an appropriate discount rate to employ. Changes in the discount rate can significantly increase or decrease our SERP obligation. For instance, a reduction in the discount rate would increase our projected benefit obligation and result in an actuarial loss. Consequently, we could be required to recognize additional pension expense in our consolidated statements of operations related to the actuarial loss in future periods if certain thresholds are met. Other actuarial assumptions include participant demographics such as the expected date of retirement, rate of salary increases and withdrawal rates, among other factors. Not only can actual experience differ

#### Table of Contents

from actuarial assumptions, but changes in any of these assumptions can also materially affect the measurement of the SERP obligation.

#### **Income Taxes**

Income taxes are accounted for in accordance with the asset and liability method. Accordingly, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their tax bases. Deferred tax assets and liabilities are measured using the enacted tax rates that are expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Deferred tax assets are reduced by a valuation allowance when, in our opinion, it is more likely than not that some or all of the deferred tax assets will not be realized. Evaluating whether deferred assets will be realized requires us to review forecasts of earnings and taxable income, among other considerations. Accordingly, the evaluation of deferred tax assets requires us to make significant judgments and forward-looking assessments regarding the amounts and availability of future taxable income.

Financial statement recognition of a tax position taken or expected to be taken in a tax return is determined based on a more likely than not threshold of that position being sustained. If the tax position meets this threshold, the benefit to be recognized is measured as the largest amount that is more than 50 percent likely to be realized upon ultimate settlement. Accounting for uncertain tax positions involves considerable judgment in assessing the future tax consequences of amounts that have been recognized in our financial statements or tax returns. The ultimate resolution of uncertain tax positions could result in amounts different from those recognized in our consolidated financial statements.

#### **Recently Issued Accounting Standards**

See Note 3 Recently Issued Accounting Standards, to our consolidated financial statements for information on our anticipated adoption of recently issued accounting standards.

### ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As of December 31, 2015, we have invested \$160.0 million in corporate-debt securities and federally-sponsored agencies. The market value of these investments varies inversely with changes in prevailing market interest rates. In general, as interest rates increase, the market value of a debt investment would be expected to decrease. Conversely, as interest rates decrease, the market value of a debt investment would be expected to increase. To date, we have not experienced significant volatility in the value of these investments. However, to address market risk, we invest in debt securities with terms no longer than three years and hold these investments to maturity so that they can be redeemed at their stated or face value. At December 31, 2015, our investments in debt securities issued by corporations and federally-sponsored agencies had a weighted average stated interest rate of approximately 0.98 percent and a weighted average maturity of 1.0 years. Many of our investments may be called by their respective issuers prior to maturity.

During sustained periods of instability and uncertainty in the financial markets, we may be subjected to additional investment-related risks that could materially affect the value and liquidity of our investments. In light of these risks, we actively monitor market conditions and developments specific to the securities and security classes in which we invest. In addition, we believe that we maintain a conservative investment approach in that we invest exclusively in unstructured, highly-rated securities with relatively short maturities that we believe reduce our exposure to undue risks. While we believe we take prudent measures to mitigate investment related risks, such risks cannot be fully eliminated, as circumstances can occur that are beyond our control.

# Table of Contents

### ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

# UNITED THERAPEUTICS CORPORATION INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm	F-2
Report of Independent Registered Public Accounting Firm on Internal Control over Financial Reporting	F-3
Consolidated Balance Sheets as of December 31, 2015 and 2014	F-4
Consolidated Statements of Operations for the years ended December 31, 2015, 2014, and 2013	F-5
Consolidated Statements of Comprehensive Income for the years ended December 31, 2015, 2014 and 2013	F-6
Consolidated Statements of Stockholders' Equity for the years ended December 31, 2015, 2014 and 2013	F-7
Consolidated Statements of Cash Flows for the years ended December 31, 2015, 2014 and 2013	F-8
Notes to Consolidated Financial Statements	F-9
F-1	

#### Table of Contents

#### Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders United Therapeutics Corporation

We have audited the accompanying consolidated balance sheets of United Therapeutics Corporation as of December 31, 2015 and 2014, and the related consolidated statements of operations, comprehensive income, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2015. Our audits also included the financial statement schedule listed in the Index at Item 15(a)(2). These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of United Therapeutics Corporation at December 31, 2015 and 2014, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2015, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

We also have audited, in accordance with the Standards of the Public Company Accounting Oversight Board (United States), United Therapeutics Corporation's internal control over financial reporting as of December 31, 2015, 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 25, 2016 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

McLean, Virginia February 25, 2016

#### Table of Contents

### Report of Independent Registered Public Accounting Firm on Internal Control over Financial Reporting

The Board of Directors and Shareholders United Therapeutics Corporation

We have audited United Therapeutics Corporation's internal control over financial reporting as of December 31, 2015, 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). United Therapeutics Corporation'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 conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). 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.

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.

In our opinion United Therapeutics Corporation maintained, in all material respects, effective internal control over financial reporting as of December 31, 2015, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of United Therapeutics Corporation as of December 31, 2015 and 2014 and the related consolidated statements of operations, comprehensive income, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2015 and our report dated February 25, 2016, expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

McLean, Virginia February 25, 2016

# UNITED THERAPEUTICS CORPORATION

### **Consolidated Balance Sheets**

# (In thousands, except share and per share data)

	December 31,				
	2015		2014		
Assets					
Current assets:					
Cash and cash equivalents	\$ 831,798	\$	397,697		
Marketable investments	121,974		297,842		
Accounts receivable, net of allowance of none for 2015 and 2014	192,827		162,287		
Inventories, net	81,334		66,927		
Other current assets	47,402		32,836		
Total current assets	1,275,335		957,589		
Marketable investments	38,002		122,658		
Goodwill and other intangible assets, net	28,378		29,465		
Property, plant, and equipment, net	495,774		478,421		
Deferred tax assets, net	192,676		198,329		
Other assets	154,280		97,948		
Total assets	\$ 2,184,445	\$	1,884,410		
Liabilities and Stockholders' Equity Current liabilities:					
Accounts payable and accrued expenses	\$ 103,433	\$	85,382		
Convertible notes	5,387		126,414		
Share tracking awards plan	274,542		282,101		
Other current liabilities	57,462		10,413		
Total current liabilities	440,824		504,310		
Other liabilities	143,974		114,526		
Total liabilities	584,798		618,836		
Commitments and contingencies Note 9					
Temporary equity	11,095		23,218		
Stockholders' equity:					
Preferred stock, par value \$.01, 10,000,000 shares authorized, no shares issued					
Series A junior participating preferred stock, par value \$.01, 100,000 shares authorized, no shares issued					
Common stock, par value \$.01, 245,000,000 shares authorized, 68,987,919 and 65,988,561 shares issued,					
and 45,760,845 and 47,107,709 shares outstanding at December 31, 2015 and 2014, respectively	690		660		
Additional paid-in capital	1,790,620		1,376,141		
Accumulated other comprehensive loss	(20,401)		(16,734)		
Treasury stock, 23,227,074 and 18,880,852 shares at December 31, 2015 and 2014, respectively	(1,902,110)		(1,185,825)		
Retained earnings	1,719,753		1,068,114		
Total stockholders' equity	1,588,552		1,242,356		
Total liabilities and stockholders' equity	\$ 2,184,445	\$	1,884,410		

See accompanying notes to consolidated financial statements.

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# UNITED THERAPEUTICS CORPORATION

# **Consolidated Statements of Operations**

# (In thousands, except per share data)

	Year Ended December 31,								
		2015		2014		2013			
Revenues:									
Net product sales	\$	1,460,570	\$	1,279,533	\$	1,106,944			
Other		5,191		8,986		10,040			
Total revenues		1,465,761		1,288,519		1,116,984			
Operating expenses:									
Research and development		245,098		242,549		299,348			
Selling, general and administrative		452,612		381,287		394,010			
Cost of product sales		69,036		125,883		131,127			
•									
Total operating expenses		766,746		749,719		824,485			
Operating income		699,015		538,800		292,499			
Other (expense) income:									
Interest expense		(4,735)		(17,592)		(18,058)			
Gain on sale of intangible asset		350,000		, , ,		, i			
Other, net		157		3,972		4,462			
Total other income (expense), net		345,422		(13,620)		(13,596)			
Income before income taxes		1,044,437		525,180		278,903			
Income tax expense		(392,798)		(185,106)		(104,343)			
		( ))		( , ,		( - ) )			
Net income	\$	651,639	\$	340,074	\$	174,560			
Tet meome	Ψ	031,037	Ψ	310,071	Ψ	171,500			
Net income per common share:									
Basic	\$	14.17	\$	7.06	\$	3.49			
Diluted	\$	12.72	\$	6.28	\$	3.28			
Dilutod	Ψ	12.72	Ψ	0.20	Ψ	3.20			
Weighted average number of common shares outstanding:									
Basic		46,000		48,176		50,076			

51,221

54,155

53,231

See accompanying notes to consolidated financial statements.

# UNITED THERAPEUTICS CORPORATION

# CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

# (In thousands)

	Year Ended December 31,					
		2015		2014		2013
Net income	\$	651,639	\$	340,074	\$	174,560
Other comprehensive (loss) income:						
Foreign currency translation loss		(5,296)		(4,789)		(1,193)
Defined benefit pension plan:						
Prior service cost arising during period, net of tax				(2,415)		
Actuarial gain arising during period, net of tax		826		2,999		2,075
Less: amortization of actuarial gain and prior service cost included in net periodic pension cost,						
net of tax		877		904		1,020
Total defined benefit pension plan, net		1,703		1,488		3,095
Unrealized loss on available-for-sale securities, net of tax		(74)		(250)		(128)
Other comprehensive (loss) gain, net of tax		(3,667)		(3,551)		1,774
1		(= ,= -,		(= ,= = = )		,,,,
Comprehensive income	\$	647,972	\$	336,523	\$	176,334

See accompanying notes to consolidated financial statements.

# UNITED THERAPEUTICS CORPORATION

# Consolidated Statements of Stockholders' Equity

# (In thousands, except share data)

Path					Accumulated			
Salane, December 31, 2012		Common	Stock	Additional Paid-in	Other Comprehensive	Treasury	Retained	Stockholders'
Balance, December 31, 2012   62,082,007   621   81,015,835   81,015,835   81,015,835   81,035,838   81,035,		Shares	Amount		•	-		
Process	Balance, December 31, 2012	62,082,007	\$ 621			(470,998)		
Adjustments	Net income						174,560	174,560
Unrealized gain on available-forespale securities   1(128)   3,095	Foreign currency translation							
1288   1288	adjustments				(1,193)			(1,193)
Defined benefit pension plan   Shares issued under employee stock plan   Shares	Unrealized gain on							
Share sissed under employee stock purchase plan   S.5,070   1   2,734	available-for-sale securities							
Purchase plane	Defined benefit pension plan				3,095			3,095
Equity component 2016 convertible notes (Note 10)								
Secretice of stack options   Secretice option		55,070	1	2,734				2,735
Repurchase of shares								
Exercise of stock options   876,115   8   26,611   26,019   278   28,010   29,009   29,000   29,000   20,000				(34,155	)			( / /
Tax benefit from exercises of non-qualified stock options   9,299   9,299   9,299   36,000						(42,439)		
Page		876,115	8	26,611				26,619
Share-based compensation         36,900         36,900         36,900           Balance, December 31, 2013         63,013,192         630         1,057,224         (13,183)         (513,437)         728,040         1,259,274           Net income         (4,789)         340,074         340,074           Foreign currency translation adjustments         (4,789)         (4,789)         (4,789)           Unrealized (floss) on available-for-sale securities         (250)         (250)           Defined benefit pension plan         1,488         1,488           Shares issued under employee stock purchase plan         45,657         1         3,329         (189,311)         3,330           Conversion of 2016 convertible notes (Note 10)         1,467,343         15         192,966         (189,311)         3,670           Equity component 2016 convertible notes (Note 10)         1,462,369         14         50,154         80,110         3,30           Exercise of stock options         1,462,369         14         50,154         80,168         11,056         11,056         11,056         11,056         11,056         11,056         11,056         12,056         10,058         10,058         10,058         10,058         10,058 </td <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td>								
Balance, December 31, 2013         63,013,192         630         1,057,224         (13,183)         (513,437)         728,040         1,259,274           Net income         (4,789)         (4,789)         340,074         340,074           Foreign currency translation adjustments         (4,789)         (4,789)         (4,789)           Unrealized (loss) on available-for-sale securities         (250)         (250)         (250)           Defined benefit pension plan         (45,657         1         3,332         (250)         (250)           Share sissued under employee stock purchase plan         (45,657         1         3,332         (14,88)         (14,88)           Conversion of 2016 convertible notes (Note 10)         1,467,343         15         192,966         (189,311)         3,670           Equity component 2016 convertible notes (Note 10)         1,467,343         15         192,966         (189,311)         3,670           Equity component 2016 convertible notes (Note 10)         1,462,369         14         50,154         50,168         50,168           Tax benefit from exercise of stock options         30,845         30,845								
Net income	Share-based compensation			36,900				36,900
Net income								
Poreign currency translation adjustments	Balance, December 31, 2013	63,013,192	630	1,057,224	(13,183)	(513,437)	728,040	1,259,274
Poreign currency translation adjustments	Net income						340,074	340,074
Unrealized (loss) on available-for-sale securities								
Available-for-sale securities   C250    C250      Defined benefit pension plan   L488   L48	adjustments				(4,789)			(4,789)
Defined benefit pension plan	Unrealized (loss) on							
Shares issued under employee stock purchase plan   45,657   1   3,329   3,330	available-for-sale securities				(250)			(250)
Description of 2016 convertible   Conversion of 2016 convertible	Defined benefit pension plan				1,488			1,488
Conversion of 2016 convertible notes (Note 10)	Shares issued under employee stock							
Notes (Note 10)	purchase plan	45,657	1	3,329				3,330
Equity component 2016 convertible notes (Note 10)	Conversion of 2016 convertible							
Notes (Note 10)	notes (Note 10)	1,467,343	15	192,966		(189,311)		3,670
Repurchase of shares   (483,077)   (483,077)								
Exercise of stock options 1,462,369 14 50,154 50,168 Tax benefit from exercises of non-qualified stock options 30,845 Share-based compensation 30,845 Share-based compensation 30,845  Balance, December 31, 2014 65,988,561 660 1,376,141 (16,734) (1,185,825) 1,068,114 1,242,356 Net income 651,639 651,639 Foreign currency translation adjustments (5,296) (5,296) Unrealized (loss) on available-for-sale securities (74) (74) Defined benefit pension plan 1,703 Shares issued under employee stock purchase plan 36,198 3,954 Conversion of 2016 convertible notes (Note 10) 1,977,577 20 324,701 (321,801) 2,920 Equity component 2016 convertible notes (Note 10) 3,020 Repurchase of shares (394,484) Exercise of stock options 985,583 10 39,301	notes (Note 10)			11,056				
Tax benefit from exercises of non-qualified stock options 30,845 Share-based compensation 30,845 30,845 Share-based compensation 30,567 30,567  Balance, December 31, 2014 65,988,561 660 1,376,141 (16,734) (1,185,825) 1,068,114 1,242,356 Net income 651,639 651,639 Foreign currency translation adjustments (5,296) (5,296) Unrealized (loss) on available-for-sale securities (74) (74) (74) Defined benefit pension plan 1,703 1,703 1,703 Shares issued under employee stock purchase plan 36,198 3,954 (2000) 3,954 (2000) (201	Repurchase of shares					(483,077)		(483,077)
Non-qualified stock options   30,845   30,845   30,567	Exercise of stock options	1,462,369	14	50,154				50,168
Share-based compensation   30,567   30,567     30,567	Tax benefit from exercises of							
Balance, December 31, 2014 65,988,561 660 1,376,141 (16,734) (1,185,825) 1,068,114 1,242,356 Net income Foreign currency translation adjustments Unrealized (loss) on available-for-sale securities Defined benefit pension plan Shares issued under employee stock purchase plan Conversion of 2016 convertible notes (Note 10) Equity component 2016 convertible notes (Note 10) Sepurchase of shares Securities Secu	non-qualified stock options			30,845				
Net income         651,639         651,639         651,639           Foreign currency translation adjustments         (5,296)         (5,296)           Unrealized (loss) on available-for-sale securities         (74)         (74)           Defined benefit pension plan         1,703         1,703           Shares issued under employee stock purchase plan         36,198         3,954         3,954           Conversion of 2016 convertible notes (Note 10)         1,977,577         20         324,701         (321,801)         2,920           Equity component 2016 convertible notes (Note 10)         3,020         3,020         3,020           Repurchase of shares         (394,484)         (394,484)         (394,484)           Exercise of stock options         985,583         10         39,301         39,311	Share-based compensation			30,567				30,567
Net income         651,639         651,639         651,639           Foreign currency translation adjustments         (5,296)         (5,296)           Unrealized (loss) on available-for-sale securities         (74)         (74)           Defined benefit pension plan         1,703         1,703           Shares issued under employee stock purchase plan         36,198         3,954         3,954           Conversion of 2016 convertible notes (Note 10)         1,977,577         20         324,701         (321,801)         2,920           Equity component 2016 convertible notes (Note 10)         3,020         3,020         3,020           Repurchase of shares         (394,484)         (394,484)         (394,484)           Exercise of stock options         985,583         10         39,301         39,311								
Net income         651,639         651,639         651,639           Foreign currency translation adjustments         (5,296)         (5,296)           Unrealized (loss) on available-for-sale securities         (74)         (74)           Defined benefit pension plan         1,703         1,703           Shares issued under employee stock purchase plan         36,198         3,954         3,954           Conversion of 2016 convertible notes (Note 10)         1,977,577         20         324,701         (321,801)         2,920           Equity component 2016 convertible notes (Note 10)         3,020         3,020         3,020           Repurchase of shares         (394,484)         (394,484)         (394,484)           Exercise of stock options         985,583         10         39,301         39,311	Balance, December 31, 2014	65,988,561	660	1,376,141	(16,734)	(1.185.825)	1.068,114	1,242,356
Foreign currency translation adjustments (5,296) (5,296)  Unrealized (loss) on available-for-sale securities (74) (74)  Defined benefit pension plan 1,703 1,703  Shares issued under employee stock purchase plan 36,198 3,954  Conversion of 2016 convertible notes (Note 10) 1,977,577 20 324,701 (321,801) 2,920  Equity component 2016 convertible notes (Note 10) 3,020  Repurchase of shares (394,484)  Exercise of stock options 985,583 10 39,301		,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		, ,	( -, /	( ) , ,		
adjustments         (5,296)         (5,296)           Unrealized (loss) on available-for-sale securities         (74)         (74)           Defined benefit pension plan         1,703         1,703           Shares issued under employee stock purchase plan         36,198         3,954         3,954           Conversion of 2016 convertible notes (Note 10)         1,977,577         20         324,701         (321,801)         2,920           Equity component 2016 convertible notes (Note 10)         3,020         3,020         3,020           Repurchase of shares         (394,484)         (394,484)         (394,484)           Exercise of stock options         985,583         10         39,301         39,311							000,000	02 2,022
Unrealized (loss) on available-for-sale securities (74) (74)  Defined benefit pension plan 1,703 1,703  Shares issued under employee stock purchase plan 36,198 3,954  Conversion of 2016 convertible notes (Note 10) 1,977,577 20 324,701 (321,801) 2,920  Equity component 2016 convertible notes (Note 10) 3,020  Repurchase of shares (394,484)  Exercise of stock options 985,583 10 39,301	•				(5,296)			(5,296)
available-for-sale securities       (74)       (74)         Defined benefit pension plan       1,703       1,703         Shares issued under employee stock purchase plan       36,198       3,954       3,954         Conversion of 2016 convertible notes (Note 10)       1,977,577       20       324,701       (321,801)       2,920         Equity component 2016 convertible notes (Note 10)       3,020       3,020         Repurchase of shares       (394,484)       (394,484)         Exercise of stock options       985,583       10       39,301       39,311	3				(4,7,4,7)			(4, 1, 1)
Defined benefit pension plan   1,703   1,703   1,703   Shares issued under employee stock purchase plan   36,198   3,954   3,954   3,954   Conversion of 2016 convertible notes (Note 10)   1,977,577   20   324,701   (321,801)   2,920   Equity component 2016 convertible notes (Note 10)   3,020   3,020   Repurchase of shares   (394,484)   (394,484)   Exercise of stock options   985,583   10   39,301   39,311					(74)			(74)
Shares issued under employee stock purchase plan 36,198 3,954 3,954  Conversion of 2016 convertible notes (Note 10) 1,977,577 20 324,701 (321,801) 2,920  Equity component 2016 convertible notes (Note 10) 3,020  Repurchase of shares (394,484)  Exercise of stock options 985,583 10 39,301 39,311								
purchase plan 36,198 3,954 3,954  Conversion of 2016 convertible notes (Note 10) 1,977,577 20 324,701 (321,801) 2,920  Equity component 2016 convertible notes (Note 10) 3,020  Repurchase of shares (394,484)  Exercise of stock options 985,583 10 39,301 39,311					,			,,,,,,
Conversion of 2016 convertible notes (Note 10)       1,977,577       20       324,701       (321,801)       2,920         Equity component 2016 convertible notes (Note 10)       3,020       3,020         Repurchase of shares       (394,484)       (394,484)         Exercise of stock options       985,583       10       39,301       39,311		36,198		3,954				3,954
notes (Note 10)         1,977,577         20         324,701         (321,801)         2,920           Equity component 2016 convertible notes (Note 10)         3,020         3,020           Repurchase of shares         (394,484)         (394,484)           Exercise of stock options         985,583         10         39,301         39,311	• •							
Equity component 2016 convertible notes (Note 10)       3,020       3,020         Repurchase of shares       (394,484)       (394,484)         Exercise of stock options       985,583       10       39,301       39,311		1,977,577	20	324,701		(321,801)		2,920
notes (Note 10)       3,020       3,020         Repurchase of shares       (394,484)       (394,484)         Exercise of stock options       985,583       10       39,301       39,311								
Repurchase of shares       (394,484)       (394,484)         Exercise of stock options       985,583       10       39,301       39,311				3,020				3,020
Exercise of stock options 985,583 10 39,301 39,311						(394,484)		(394,484)
		985,583	10	39,301				
	_			37,426				37,426

Tax benefit from exercises of non-qualified stock options

non-qualified stock options			
Share-based compensation	6,077	6,077	
Balance, December 31, 2015	68,987,919 \$ 690 \$ 1,790,620 \$	(20,401) \$ (1,902,110) \$ 1,719,753 \$ 1,588,552	

See accompanying notes to consolidated financial statements.

# UNITED THERAPEUTICS CORPORATION

# **Consolidated Statements of Cash Flows**

# (In thousands)

	Year Ended December 31,							
		2015	2013					
Cash flows from operating activities:								
Net income	\$	651,639	\$	340,074	\$	174,560		
Adjustments to reconcile net income to net cash provided by operating activities:								
Depreciation and amortization		32,921		32,245		31,259		
Share-based compensation expense		280,254		190,054		320,786		
Gain on sale of intangible asset		(350,000)						
Amortization of debt discount and debt issue costs		5,941		12,456		12,601		
Amortization of discount or premium on investments		2,132		5,231		4,501		
Other		(515)		6,493		3,182		
Excess tax benefits from share-based compensation		(37,426)		(30,845)		(9,299)		
Changes in operating assets and liabilities:								
Accounts receivable		(30,540)		(35,689)		(10,027)		
Inventories		(6,794)		(21,032)		(12,394)		
Accounts payable and accrued expenses		16,972		(6,753)		7,507		
Other assets and liabilities		(181,823)		(136,975)		(97,409)		
Net cash provided by operating activities		382,761		355,259		425,267		
Cash flows from investing activities:								
Purchases of property, plant and equipment, net		(49,792)		(47,439)		(31,910)		
Purchases of held-to-maturity investments		(62,781)		(118,672)		(762,198)		
Maturities of held-to-maturity investments		320,369		549,576		529,900		
Gain on sale of intangible asset		350,000						
Purchase of investments under the cost method, net		(54,217)		(45,000)		(30,766)		
Net cash provided by (used in) investing activities		503,579		338,465		(294,974)		
		·		,				
Cash flows from financing activities:								
Principal payments of debt		(133,150)		(177,800)		(1,320)		
Payments to repurchase common stock		(394,484)		(483,077)		(42,439)		
Proceeds from line of credit		( , - ,		140,000		( ,,		
Payments on the line of credit				(140,000)				
Proceeds from exercise of stock options		39,311		50,168		26,611		
Issuance of stock under employee stock purchase plan		3,954		3,329		2,734		
Excess tax benefits from share-based compensation		37,426		30,845		9,299		
•								
Net cash used in financing activities		(446,943)		(576,535)		(5,115)		
The cash asea in financing activities		(110,515)		(370,333)		(3,113)		
Effect of exchange rate changes on cash and cash equivalents		(5,296)		(3,750)		(319)		
Net increase in cash and cash equivalents		434,101		113,439		124,859		
Cash and cash equivalents, beginning of year		397,697		284,258		159,399		
Cash and cash equivalents, organing of year		371,071		207,230		137,377		
Cook and each equivalents and of year	¢	921 709	¢	207 607	Ф	204 250		
Cash and cash equivalents, end of year	\$	831,798	Þ	397,697	\$	284,258		

Supplemental cash flow information:			
Cash paid for interest	\$ 1,015	\$ 5,453	\$ 5,518
Cash paid for income taxes	\$ 293,331	\$ 195,564	\$ 142,140
Non-cash investing and financing activities:			
Acquisitions non-cash consideration		\$ 5,200	\$
Non-cash additions to property, plant and equipment	\$ 1,078	\$ 3,150	\$ 9,018
Issuance of common stock upon conversion of convertible notes	321,801	\$ 189,311	\$

See accompanying notes to consolidated financial statements.

#### UNITED THERAPEUTICS CORPORATION

#### **Notes to Consolidated Financial Statements**

#### 1. Organization and Business Description

United Therapeutics Corporation is a biotechnology company focused on the development and commercialization of innovative products to address the unmet medical needs of patients with chronic and life-threatening diseases.

We have approval from the United States Food and Drug Administration (FDA) to market the following therapies: Remodulin® (treprostinil) Injection (Remodulin), Tyvaso® (treprostinil) Inhalation Solution (Tyvaso), Adcirca® (tadalafil) Tablets (Adcirca), Orenitram® (treprostinil) Extended-Release Tablets (Orenitram) and Unituxin® (dinutuximab) Injection (Unituxin). Remodulin has also been approved in various countries outside the United States, and Unituxin was granted marketing authorization by the European Medicines Agency in August 2015. Tyvaso is also approved in Israel. We commenced commercial sales of Orenitram and Unituxin in the U.S. during the second quarter of 2014 and the third quarter of 2015, respectively.

As used in these notes to the consolidated financial statements, unless the context otherwise requires, the terms "we", "us", "our", and similar terms refer to United Therapeutics Corporation and its consolidated subsidiaries.

#### 2. Summary of Significant Accounting Policies

#### Basis of Presentation and Principles of Consolidation

The accompanying consolidated financial statements of United Therapeutics Corporation and its wholly owned subsidiaries have been prepared in accordance with accounting principles generally accepted in the United States (GAAP). All intercompany balances and transactions have been eliminated in consolidation.

In the operating section of our statement of cash flows, we reclassified the prior period amounts within "current and deferred income tax expense" to "other assets and liabilities" to conform with the current period presentation.

### Use of Estimates

The preparation of the consolidated financial statements in accordance with GAAP requires our management to make estimates and assumptions that affect reported amounts of assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. We base our estimates on assumptions regarding historical experience, currently available information and anticipated developments that we believe are reasonable and appropriate. However, because the use of estimates involves an inherent degree of uncertainty, actual results could differ from those estimates. Our significant accounting policies that require use of subjective and/or complex judgment and estimates impact the following financial statement areas: revenue recognition, share-based compensation, marketable investments, fair value measurements (including those relating to our acquisitions), income taxes, goodwill and other intangible assets, and obligations related to our Supplemental Executive Retirement Plan.

#### Fair Value of Financial Instruments

The carrying amounts of cash and cash equivalents, accounts receivables, accounts payable, and accrued expenses approximate fair value because of their short maturities. The fair values of our

#### Table of Contents

#### UNITED THERAPEUTICS CORPORATION

#### **Notes to Consolidated Financial Statements (Continued)**

#### 2. Summary of Significant Accounting Policies (Continued)

marketable investments and 1.0 percent Convertible Senior Notes due September 15, 2016 (Convertible Notes) are reported in Note 4 *Investments* and Note 5 *Fair Value Measurements*, respectively.

#### Fair Value Measurements

Fair value is a market-based measurement, not an entity-specific measurement. The objective of a fair value measurement is to estimate the price to sell an asset or transfer a liability in an orderly transaction between market participants at the measurement date under current market conditions. Such transactions to sell an asset or transfer a liability are assumed to occur in the principal market for that asset or liability, or in the absence of the principal market, the most advantageous market for the asset or liability.

Assets and liabilities subject to fair value measurement disclosures are required to be classified according to a three-level fair value hierarchy with respect to the inputs (or assumptions) used to determine fair value. Observable inputs such as unadjusted quoted market prices for identical assets or liabilities are given the highest priority within the hierarchy (Level 1). When observable inputs are unavailable, fair value is measured using unobservable inputs i.e., inputs that a reporting entity believes market participants would use in pricing that are developed based on the best information available. Unobservable inputs are given the lowest priority within the hierarchy (Level 3). The level in which an asset or liability is disclosed within the fair value hierarchy is based on the lowest level input that is significant to the related fair value measurement in its entirety. The guidance under the fair value measurement framework applies to other existing accounting guidance in the Financial Accounting Standard Board (FASB) codification that requires or permits fair value measurements. Refer to related disclosures at Note 5 *Fair Value Measurements* to these consolidated financial statements.

### Cash Equivalents

Cash equivalents consist of highly liquid investments with maturities of three months or less from the date of acquisition and include money market funds, commercial paper, and certificates of deposit.

#### Marketable Investments

Substantially all of our marketable investments are debt securities that we classify as held-to-maturity because of our positive intent and ability to hold the securities until maturity. Held-to-maturity securities are classified as either current or non-current assets on our consolidated balance sheets based on their contractual maturity dates and are recorded at amortized cost, adjusted for the amortization of discounts or premiums. Related discounts and premiums are amortized over the term of these securities as an adjustment to yield using the effective interest method.

We monitor our investment portfolio for impairment quarterly or more frequently if circumstances warrant. In the event that the carrying value of an investment exceeds its fair value and the decline in value is determined to be other-than-temporary, we record an impairment charge within earnings attributable to the estimated credit loss. In determining whether a decline in the value of an investment is other-than-temporary, we evaluate currently available factors that may include, among others: (1) general market conditions; (2) the duration and extent to which fair value has been less than the carrying value; (3) the investment issuer's financial condition and business outlook; and (4) our

### UNITED THERAPEUTICS CORPORATION

#### **Notes to Consolidated Financial Statements (Continued)**

#### 2. Summary of Significant Accounting Policies (Continued)

assessment as to whether it is more likely than not that we will be required to sell a security prior to recovery of its amortized cost basis.

#### Trade Receivables

Trade receivables consist of short-term amounts due from customers and are stated at the amount we expect to collect. We establish an allowance for doubtful accounts, if any, based on our assessment of the collectability of specific customer accounts.

#### Inventories

Inventories are stated at the lower of cost (first-in, first-out method) or market (current replacement cost) and consist of the following, net of reserves (in thousands):

	As of December 31,								
	2015		2014						
Raw materials	\$ 23,093	\$	21,317						
Work-in-progress	22,494		15,994						
Finished goods	35,747		29,616						
Total inventories	\$ 81,334	\$	66,927						

### Goodwill and Other Intangible Assets

The carrying amount of goodwill is not amortized but is subject to annual impairment testing. We conduct our impairment testing of goodwill annually during the fourth quarter, or more frequently, if impairment indicators exist. Initially, we evaluate various pertinent qualitative factors to assess whether it is more likely than not that the fair value of a reporting unit to which goodwill has been assigned is less than its carrying value. Such qualitative factors can include, among others: (1) industry and market conditions; (2) present and anticipated sales and cost factors; and (3) overall financial performance. If we conclude based on our qualitative assessment that it is more likely than not that the fair value of a reporting unit is less than its carrying value, we then measure the fair value of the reporting unit and compare its fair value to its carrying value (Step 1 of the goodwill impairment test). If the carrying amount of the reporting unit exceeds its fair value, then the amount of an impairment loss, if any, is measured as the excess of the recorded amount of goodwill over its implied fair value (Step 2 of the goodwill impairment test). The Company used a qualitative assessment for its goodwill impairment testing for 2015 and 2014. The Company's evaluation of goodwill completed during the years ended December 31, 2015 and 2014 resulted in no impairment losses.

Indefinite-lived intangible assets are not amortized but are evaluated annually or more frequently for impairment if impairment indicators exist. The Company's indefinite-lived intangible assets include purchased in-process research and development projects, which were measured at their estimated fair values as of their acquisition dates. The Company used a qualitative assessment for its indefinite-lived intangible asset impairment testing. The Company's evaluation of indefinite-lived intangible assets completed during the years ended December 31, 2015 and 2014 resulted in no impairment losses.

Intangible assets subject to amortization are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an intangible asset may not be recoverable.

### UNITED THERAPEUTICS CORPORATION

### **Notes to Consolidated Financial Statements (Continued)**

### 2. Summary of Significant Accounting Policies (Continued)

Impairment losses are measured and recognized to the extent the carrying value of such assets exceeds their fair value. The Company recorded no impairment losses during the years ended December 31, 2015 and 2014.

Goodwill and other intangible assets comprise the following (in thousands):

	As of December 31, 2015 Accumulated						As of December 31, 2014 Accumulated					
		Gross	Amo	rtization		Net		Gross	Amo	rtization		Net
Goodwill	\$	10,264	\$		\$	10,264	\$	10,264	\$		\$	10,264
Other intangible assets:												
Technology, patents and trade names		6,494		(4,691)		1,803		6,494		(4,100)		2,394
In-process, research and development		15,500				15,500		15,500				15,500
Customer relationships and non-compete												
agreements		4,369		(3,558)		811		4,369		(3,062)		1,307
Contract-based		1,270		(1,270)				1,270		(1,270)		
Total	\$	37,897	\$	(9,519)	\$	28,378	\$	37,897	\$	(8,432)	\$	29,465

Related amortization expense for the years ended December 31, 2015, 2014 and 2013, was \$1.1 million, \$1.4 million and \$2.6 million, respectively. As of December 31, 2015, aggregate amortization expense relating to definite lived intangible assets for each of the five succeeding years and thereafter is estimated as follows (in thousands):

Year Ended December 31,	
2016	\$ 621
2017	456
2018	125
2019	125
2020	125
Thereafter	1,162
	\$ 2,614

In September 2015, we sold the Rare Pediatric Priority Review Voucher (PPRV) we received from the FDA in connection with the approval of Unituxin for \$350.0 million in cash. The proceeds from the sale of the PPRV were recognized as a gain on the sale of an intangible asset, as the PPRV did not have a carrying value on our consolidated balance sheet at the time of sale.

### UNITED THERAPEUTICS CORPORATION

### **Notes to Consolidated Financial Statements (Continued)**

#### 2. Summary of Significant Accounting Policies (Continued)

### Property, Plant and Equipment

Property, plant and equipment is recorded at cost and depreciated over its estimated useful life using the straight-line method. The estimated useful lives of property, plant and equipment by major category are as follows:

Land improvements	15 Years
Buildings	25 - 39 Years
Building improvements	10 - 39 Years
Furniture, equipment and vehicles	3 - 20 Years
Leasehold improvements	Remaining lease term, or the estimated useful life of the
	improvement, whichever is shorter

Property, plant and equipment consists of the following (in thousands):

	As of December 31,					
		2015		2014		
Land and land improvements	\$	61,091	\$	46,141		
Buildings, building improvements and leasehold improvements		418,245		413,066		
Buildings under construction		26,458		17,379		
Furniture, equipment and vehicles		144,862		136,805		
		650,656		613,391		
Less accumulated depreciation		(154,882)		(134,970)		
Property, plant and equipment, net	\$	495,774	\$	478,421		

Depreciation expense for the years ended December 31, 2015, 2014 and 2013 was \$31.8 million, \$30.8 million and \$28.6 million, respectively.

Buildings under construction consists of direct costs relating to our construction projects and includes capitalized interest.

### Treasury Stock

Repurchased treasury stock is recorded at cost, including commissions and fees. Treasury stock acquired from the convertible note hedge on our Convertible Notes is recorded at the fair value on the acquisition date closing price of our common stock. The cost of treasury shares sold is determined using the first-in, first-out method. Related gains and losses on sales of treasury stock are recognized as adjustments to stockholders' equity.

#### Revenue Recognition

Remodulin, Tyvaso, Orenitram and Unituxin

We sell Remodulin, Tyvaso, Orenitram and Unituxin to distributors under similar contractual arrangements. We recognize sales of these products when title and risk of ownership pass to our

Table of Contents

#### UNITED THERAPEUTICS CORPORATION

#### **Notes to Consolidated Financial Statements (Continued)**

#### 2. Summary of Significant Accounting Policies (Continued)

distributors upon satisfactory delivery *i.e.*, when all of our performance obligations under our distribution agreements have been satisfied. We record sales of these products net of various product sales allowances in the period that associated revenues are recognized. These sales allowances include estimated rebates, prompt payment discounts, sales returns and service fees paid to our distributors. Calculating these sales allowances involves the use of significant estimates and judgments and information obtained from external sources.

We derive our provisions for rebates from an analysis of historical levels of rebates to both state Medicaid agencies and commercial third-party payers by product, relative to sales of each product. In addition, for Orenitram patients, we determine our obligation for prescription drug discounts required by Medicare Part D for patients within the coverage gap based on estimations of the number of patients and the period that such patients will remain within the coverage gap. In formulating our estimates, we also consider the impact of anticipated changes in our product pricing, if any, sales trends and government rebate programs, particularly as they relate to eligibility requirements and/or rebate pricing.

We estimate prompt pay discounts based on observed payment behavior. Our distributors have routinely taken advantage of these discounts and we expect them to continue to do so.

Our distributors do not possess return rights for Remodulin, Tyvaso and Orenitram; however, the sales terms for Unituxin include return rights that extend throughout the distribution channel. We provide exchange rights for all products in the event that product is damaged during shipment or expires. Exchanges for damaged product are highly infrequent. In the event that Remodulin, Tyvaso, Orenitram, or Unituxin has been damaged during shipment and we have been promptly notified as required under our distribution agreements, we do not recognize revenue on that shipment until damaged product has been replaced. Replacement of damaged product generally occurs within several days after notification of the damage. Furthermore, the number of product exchanges due to expiration has been minimal because we sell Remodulin, Tyvaso and Orenitram with a remaining shelf life in excess of one year and our distributors typically carry a thirty- to sixty-day supply of our treprostinil-based products at any given time. In addition, we closely track inventory levels held by our distributors. Except for contractual minimum inventory levels to prevent shortages of treprostinil-based drug supply, we do not require, nor do we provide incentives for our distributors to assume, inventory levels of Remodulin, Tyvaso, Orenitram or Unituxin beyond what would be considered reasonable and customary in the ordinary course of business.

We pay our distributors for contractual services rendered and accrue for related fees based on contractual rates applied to the estimated units of service provided by distributors for a given financial reporting period.

The financial effects of exchange rights for Remodulin, Tyvaso, Orenitram and Unituxin have been immaterial and we expect the volume of exchanges to be consistent with historical levels. Specifically, exchanges of Remodulin, Tyvaso, Orenitram and Unituxin have comprised substantially less than one percent of the volume of the units that we sell. Because historical and anticipated future exchanges of Remodulin, Tyvaso, Orenitram and Unituxin have been and are expected to be immaterial, we do not record a reserve for estimated exchange rights in the period of sale. Lastly, we closely monitor product exchange data for all of these therapies to ensure that our assumptions continue to be reasonable, appropriate and current.

#### Table of Contents

### UNITED THERAPEUTICS CORPORATION

#### **Notes to Consolidated Financial Statements (Continued)**

#### 2. Summary of Significant Accounting Policies (Continued)

Adcirca

Adcirca is manufactured for us by Eli Lilly and Company (Lilly) and distributed through Lilly's pharmaceutical wholesaler network. Specifically, Lilly handles all of the administrative functions associated with the sale of Adcirca on our behalf, including the receipt and processing of customer purchase orders, shipment to customers, and invoicing and collection of customer payments. In addition, the sales terms for Adcirca include return rights that extend throughout the distribution channel. We recognize sales of Adcirca on a gross basis (net of allowances) upon delivery to customers due to the following factors: (1) we are responsible for the acceptability of the product purchased by wholesalers; (2) we bear all inventory risk, as title and risk of loss pass to us at the shipping point from Lilly's manufacturing facility; (3) we assume credit risk if Lilly is unable to collect amounts due from customers; and (4) we assume the risk and cost of a product recall, if required.

We recognize sales of Adcirca net of: (1) estimated government-based and commercial payer rebates; (2) prompt pay discounts; (3) allowances for product returns; and (4) wholesaler fees. We estimate our liability for rebates based on an analysis of historical levels of rebates to both Medicaid and commercial third-party payers and we consider the impact of sales trends, changes in government and commercial rebate programs and anticipated changes in Adcirca's pricing. In addition, for Adcirca patients, we determine our obligation for prescription drug discounts required by Medicare Part D for patients within the coverage gap based on estimations of the number of patients and the period that such patients will remain within the coverage gap. We base our estimates for prompt pay discounts on observed customer payment behavior and expectations regarding the future utilization of such discounts. We derive our allowance for returns of Adcirca based on historical return rates accumulated since the commercial launch of Adcirca in 2009. To date, we have not identified any unusual patterns in the volume of prescriptions relative to sales that would warrant reconsideration of, or adjustment to, the methodology we currently employ to estimate our allowance for returns. Lastly, wholesaler fees are based on contractual percentages of sales to wholesalers.

### Research and Development

Research and development costs are expensed as incurred except for refundable payments made in advance of services to be provided to us. Related expenses consist of internal labor and overhead, costs to acquire pharmaceutical products and product rights for development, materials used in clinical trials and amounts paid to third parties for services and materials relating to drug development and clinical trials.

We recognize the following as research and development expense in the period related costs are incurred:

Costs associated with in-house or contracted production activities prior to receiving FDA approval for such facilities, or for major unproven changes to our production processes;

Costs incurred in licensing the rights to technologies in the research and development stage that have no alternative future uses; and

Up-front payments made in connection with arrangements to obtain license and distribution rights to pharmaceutical product candidates prior to regulatory approval, absent any alternative future uses.

#### Table of Contents

#### UNITED THERAPEUTICS CORPORATION

### **Notes to Consolidated Financial Statements (Continued)**

#### 2. Summary of Significant Accounting Policies (Continued)

#### Share-Based Compensation

Our share tracking award plans require cash settlement upon exercise and are classified as a liability. Accordingly, the fair value of related cash-settled awards is re-measured at each reporting date until awards are exercised or are otherwise no longer outstanding. Related changes in the fair value of outstanding cash-settled awards at each financial reporting date are recognized as adjustments to share-based compensation expense.

Generally, the fair value of a stock option grant is measured on its grant date and related compensation expense is recognized ratably over the requisite service period. For stock option awards that vest immediately upon issuance, compensation expense is recognized in its entirety based on the grant-date fair value. We issue new shares of our common stock upon the exercise of stock options.

We measure the fair value of stock to be purchased through our employee stock purchase plan at the beginning of an offering period, or grant date, and recognize related compensation expense ratably over the requisite service period (the offering period). We issue new shares of our common stock upon the end of each offering period, or exercise date.

#### **Income Taxes**

Income taxes are accounted for in accordance with the asset and liability method. Accordingly, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their tax bases. Deferred tax assets and liabilities are measured using the enacted tax rates that are expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in the period that includes the enactment date. Deferred tax assets are reduced by a valuation allowance when, in our judgment, it is more likely than not that some or all of the deferred tax assets will not be realized.

Financial statement recognition of a tax position taken or expected to be taken in a tax return is determined based on a more likely than not threshold of that position being sustained. If the tax position meets this threshold, the benefit to be recognized is measured as the largest amount that is more than 50 percent likely to be realized upon ultimate settlement. It is our policy to record interest and penalties related to uncertain tax positions as a component of income tax expense.

### Earnings (Loss) per Share

Basic earnings per share is computed by dividing net income by the weighted average number of shares of common stock outstanding during the period. Diluted earnings per common share is computed by dividing net income by the weighted average number of shares of common stock outstanding during the period, plus the potential dilutive effect of other securities if such securities were converted or exercised. During periods in which we incur net losses, both basic and diluted loss per share is calculated by dividing the net loss by the weighted average shares outstanding potentially dilutive securities are excluded from the calculation because their effect would be anti-dilutive.

#### Table of Contents

### UNITED THERAPEUTICS CORPORATION

#### **Notes to Consolidated Financial Statements (Continued)**

#### 2. Summary of Significant Accounting Policies (Continued)

#### Concentrations of Credit Risk, Products, Revenues and Customers

Concentration of credit risk

Financial instruments that are exposed to credit risk consist of cash, money market funds, commercial paper, marketable investments, and trade receivables. We maintain our cash and money market funds with financial institutions that are federally insured. While balances deposited in these institutions often exceed Federal Deposit Insurance Corporation limits, we have not experienced any losses on related accounts to date. Furthermore, we limit our risk exposure by maintaining funds in financial institutions that we believe are creditworthy and financially sound. Our investments in marketable debt securities have been issued by corporate entities and federally-sponsored enterprises with high credit ratings. We mitigate investment risks by investing in highly-rated securities with relatively short maturities that we believe do not subject us to undue investment or credit risk. In addition, our investment policy does not provide for investments in complex or structured financial instruments. At any given time, our trade receivables are concentrated among a small number of principal customers. If any of these financial institutions, issuers or customers fail to perform their obligations under the terms of these financial instruments, our maximum exposure to potential losses would be equal to amounts reported on our consolidated balance sheets.

#### Concentration of products, revenues, and customers

In the United States, through 2013 we sold Remodulin, Tyvaso, and Orenitram to three specialty pharmaceutical distributors: Accredo Health Group Inc. (Accredo), CuraScript Inc. (CuraScript) and CVS Caremark. In December 2013, the operations of CuraScript were integrated into Accredo's operations as a result of the 2012 acquisition of Medco Health Solutions, Inc., the parent company of Accredo, by Express Scripts, Inc., the parent company of CuraScript, and we consolidated our distribution agreements with CuraScript and Accredo into one contract for each product. During the years ended December 31, 2015, 2014 and 2013, net product sales of Remodulin, Tyvaso and Orenitram to these distributors accounted for 72 percent, 74 percent and 76 percent, respectively, of our total revenues. During the years ended December 31, 2015, 2014 and 2013, net product sales of Remodulin accounted for 39 percent, 43 percent and 44 percent, respectively, of our total revenues, while net product sales of Tyvaso during this period comprised 32 percent, 36 percent and 39 percent, respectively of our total revenues. During the years ended December 31, 2015 and 2014, net product sales of Orenitram accounted for 8 percent and 3 percent, respectively, of our total revenues.

At December 31, 2015 and 2014, 50 percent and 52 percent, respectively, of our accounts receivable was due from U.S.-based specialty distributors

During the years ended December 31, 2015, 2014 and 2013, we derived 55 percent, 58 percent and 57 percent of our total revenues from one customer. Estimated total revenues from that customer were as follows (in thousands):

#### Year Ended December 31,

	2015	2014	2013
Accredo Health Group, Inc.	\$ 807,012	\$ 744,765	\$ 632,599

Table of Contents

#### UNITED THERAPEUTICS CORPORATION

#### **Notes to Consolidated Financial Statements (Continued)**

#### 3. Recently Issued Accounting Standards

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers* (ASU 2014-09). ASU 2014-09 will eliminate transaction-specific and industry-specific revenue recognition guidance under current GAAP and replace it with a principle-based approach for determining revenue recognition. ASU 2014-09 will require that companies recognize revenue based on the value of transferred goods or services as they occur in the contract. ASU 2014-09 also will require additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. ASU 2014-09 is effective for annual reporting periods beginning after December 15, 2016. Early application is not permitted. ASU 2014-09 allows for either full retrospective or modified retrospective adoption. On July 9, 2015, the FASB issued ASU No. 2015-14, *Revenue from Contracts with Customers (Topic 606); Deferral of the Effective Date*, which (1) delays the effective date of ASU 2014-09 by one year to annual periods beginning after December 15, 2017; and (2) allows early adoption of the ASU by all entities as of the original effective date for public entities. We are evaluating the transition method we will elect and the effects of the adoption of this ASU on our financial statements.

In April 2015, the FASB issued ASU No. 2015-03, Simplifying the Presentation of Debt Issuance Costs (ASU 2015-03), which requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. ASU 2015-03 requires retrospective adoption and will be effective for us beginning in our first quarter of 2016. Early adoption is permitted. We do not expect the adoption of ASU 2015-03 to have a material impact on our financial statements.

In July 2015, the FASB issued ASU No. 2015-11, *Simplifying the Measurement of Inventory* (ASU 2015-11), which requires that inventory be measured at the lower of cost or net realizable value for entities using first-in, first-out or average cost methods. ASU 2015-11 should be applied prospectively and will be effective for fiscal years beginning after December 15, 2016, and for interim periods within those fiscal years, with early adoption permitted. We are evaluating the effect of adoption on our financial statements.

In November 2015, the FASB issued ASU No. 2015-17, *Balance Sheet Classification of Deferred Taxes* (ASU 2015-17), which requires deferred tax assets and liabilities to be classified as noncurrent in a classified statement of financial position. The guidance is effective for financial statements issued for annual periods beginning after December 15, 2017, and interim periods within annual periods beginning after December 15, 2018. Earlier application is permitted for all entities as of the beginning of an interim or annual reporting period. This amendment may be applied either prospectively or retrospectively to all periods presented.

We early adopted the provisions of ASU 2015-17 in the fourth quarter of 2015 on a retrospective basis. The adoption of this ASU will simplify the presentation of deferred income taxes and reduce complexity without decreasing the usefulness of information provided to users of financial statements. The adoption resulted in an \$18.1 million and \$16.6 million decrease in other current assets and a corresponding increase to deferred tax assets, net in our consolidated balance sheets at December 31, 2015 and 2014, respectively. The adoption had no impact on our results of operations or cash flows.

# Table of Contents

# UNITED THERAPEUTICS CORPORATION

# Notes to Consolidated Financial Statements (Continued)

### 4. Investments

# Marketable Investments

Held-to-Maturity Investments

Marketable investments classified as held-to-maturity consist of the following (in thousands):

As of December 31, 2015	Amortized Cost		Gross Unrealized Gains		Losses		Fair Value
Government-sponsored enterprises	\$	53,254	\$	3	\$	(119) \$	53,138
Corporate notes and bonds		106,722		37		(67)	106,692
Total	\$	159,976	\$	40	\$	(186) \$	159,830
Reported under the following captions on the consolidated balance sheet:							
Current marketable investments	\$	121,974					
Noncurrent marketable investments		38,002					
	\$	159,976					

As of December 31, 2014	A	mortized Cost	Uı	Gross realized Gains	ι	Gross Inrealized Losses	Fair Value
Government-sponsored enterprises	\$	127,212	\$	118	\$	(39)	\$ 127,291
Corporate notes and bonds		293,288		260		(108)	293,440
Total	\$	420,500	\$	378	\$	(147)	\$ 420,731
Reported under the following captions on the consolidated balance sheet:							
Current marketable investments	\$	297,842					
Noncurrent marketable investments		122,658					
	\$	420,500					

### UNITED THERAPEUTICS CORPORATION

### **Notes to Consolidated Financial Statements (Continued)**

#### 4. Investments (Continued)

The following table summarizes gross unrealized losses and the length of time marketable investments have been in a continuous unrealized loss position (in thousands):

	As of December 31,									
		20			2014					
		Gross Fair Unrealized Value Loss		Unrealized		Unrealized Fa		Fair Value		Gross nrealized Loss
Government-sponsored enterprises:										
Continuous unrealized loss position less than one year	\$	48,138	\$	(119)	\$	15,293	\$	(39)		
Continuous unrealized loss position greater than one year										
		48,138		(119)		15,293		(39)		
Corporate notes and bonds:										
Continuous unrealized loss position less than one year		63,840		(67)		86,824		(97)		
Continuous unrealized loss position greater than one year						3,443		(11)		
		63,840		(67)		90,267		(108)		
Total	\$	111,978	\$	(186)	\$	105,560	\$	(147)		

We attribute the unrealized losses on held-to-maturity securities as of December 31, 2015 and 2014, to the variability in related market interest rates. We do not intend to sell these securities, nor is it more likely than not that we will be required to sell them prior to the end of their contractual terms. Furthermore, we do not believe that these securities expose us to undue market risk or counterparty credit risk. As such, we do not consider these securities to be other than temporarily impaired.

The following table summarizes the contractual maturities of held-to-maturity marketable investments (in thousands):

	As of December 31, 2015								
	A	mortized		Fair					
		Cost		Value					
Due in less than one year	\$	121,974	\$	121,932					
Due in one to two years		38,002		37,898					
Due in three to five years									
Due after five years									
Total	\$	159,976	\$	159,830					

#### Investments Held at Cost

As of December 31, 2015, we maintain in the aggregate, non-controlling equity investments of approximately \$137.2 million in privately-held corporations, including a \$100.0 million investment in the preferred stock of Synthetic Genomics Inc. (SGI), which we purchased in two separate \$50.0 million transactions in May 2014 and September 2015. We account for these investments under the cost method since we do not have the ability to exercise significant influence over these companies and their

#### **Table of Contents**

### UNITED THERAPEUTICS CORPORATION

#### **Notes to Consolidated Financial Statements (Continued)**

#### 4. Investments (Continued)

fair values are not readily determinable. The fair value of these investments has not been estimated at December 31, 2015, as we have not identified any events or developments indicating that their carrying amounts may be impaired. We include these investments within other assets on our accompanying consolidated balance sheets.

In addition to the SGI investments noted above, we entered into a separate multi-year research and development collaboration agreement with SGI in May 2014, whereby SGI will develop engineered primary pig cells with modified genomes for use in our xenotransplantation program. This collaboration was initially focused primarily on lungs and was expanded in September 2015 to include an additional focus on kidneys. Under this agreement, each party assumes its own research and development costs and SGI may receive royalties and milestone payments from development and commercialization of organs.

#### 5. Fair Value Measurements

Assets and liabilities subject to fair value measurements are required to be disclosed within a fair value hierarchy. The fair value hierarchy ranks the quality and reliability of inputs used to determine fair value. Accordingly, assets and liabilities carried at, or permitted to be carried at, fair value are classified within the fair value hierarchy in one of the following categories based on the lowest level input that is significant in measuring fair value:

Level 1 Fair value is determined by using unadjusted quoted prices that are available in active markets for identical assets and liabilities.

Level 2 Fair value is determined by using inputs other than Level 1 quoted prices that are directly or indirectly observable. Inputs can include quoted prices for similar assets and liabilities in active markets or quoted prices for identical assets and liabilities in inactive markets. Related inputs can also include those used in valuation or other pricing models such as interest rates and yield curves that can be corroborated by observable market data.

Level 3 Fair value is determined by using inputs that are unobservable and not corroborated by market data. Use of these inputs involves significant and subjective judgment.

We account for certain assets and liabilities at fair value and rank these assets within a fair value hierarchy (Level 1, Level 2 or Level 3). Our other current assets and our other current liabilities have

# UNITED THERAPEUTICS CORPORATION

### **Notes to Consolidated Financial Statements (Continued)**

### **5. Fair Value Measurements (Continued)**

fair values that approximate their carrying values. Assets and liabilities subject to fair value measurements are as follows (in thousands):

	As of December 31, 2015									
	]	Level 1		Level 2	Level 3			Balance		
Assets										
Money market funds <sup>(1)</sup>	\$	496,434	\$		\$		\$	496,434		
Federally-sponsored and corporate debt securities <sup>(2)</sup>				159,830				159,830		
Total assets	\$	496,434	\$	159,830	\$		\$	656,264		
Liabilities										
Convertible notes due 2016 <sup>(3)</sup>	\$	15,998	\$		\$		\$	15,998		
Contingent consideration <sup>(4)</sup>						9,400		9,400		
Total liabilities	\$	15,998	\$		\$	9,400	\$	25,398		

	As of December 31, 2014										
	]	Level 1		Level 2	L	evel 3	]	Balance			
Assets											
Money market funds <sup>(1)</sup>	\$	298,416	\$		\$		\$	298,416			
Federally-sponsored and corporate debt securities <sup>(2)</sup>				420,731				420,731			
Total assets	\$	298,416	\$	420,731	\$		\$	719,147			
Liabilities											
Convertible notes due 2016 <sup>(3)</sup>	\$	388,153	\$		\$		\$	388,153			
Contingent consideration <sup>(4)</sup>						11,502		11,502			
Total liabilities	\$	388,153	\$		\$	11,502	\$	399,655			

Included in cash and cash equivalents on the accompanying consolidated balance sheets.

<sup>(2)</sup>Included in current and non-current marketable investments on the accompanying consolidated balance sheets. The fair value of these securities is principally measured or corroborated by trade data for identical securities in which related trading activity is not

sufficiently frequent to be considered a Level 1 input or comparable securities that are more actively traded. See also Note 4 *Investments Marketable Investments Held-to-Maturity Investments* to these consolidated financial statements.

Included in convertible notes on the accompanying consolidated balance sheets. The fair value of our Convertible Notes is estimated using Level 1 observable inputs since our Convertible Notes are trading with sufficient frequency such that we believe related pricing can be used as the primary basis for measuring their fair value. As of December 31, 2015 and December 31, 2014, the fair value of the Convertible Notes was substantially higher than their book value. This was primarily due to the excess conversion value of the notes compared to the notes' par value, and the fact that any such excess would be paid in shares of our common stock.

#### UNITED THERAPEUTICS CORPORATION

#### **Notes to Consolidated Financial Statements (Continued)**

### **5. Fair Value Measurements (Continued)**

(4)
Included in other liabilities on the accompanying consolidated balance sheets. The fair value of contingent consideration has been estimated using probability weighted discounted cash flow models (DCF). The DCF incorporates Level 3 inputs including estimated discount rates that we believe market participants would consider relevant in pricing and the projected timing and amount of cash flows, which are estimated and developed, in part, based on the requirements specific to each acquisition agreement. We analyze and

evaluate these fair value measurements quarterly to determine whether valuation inputs continue to be relevant and appropriate or whether current period developments warrant adjustments to valuation inputs and related measurements.

### 6. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following by major categories (in thousands):

	As of December 31,					
		2015		2014		
Accounts payable	\$	7,502	\$	6,995		
Accrued expenses:						
Sales related (royalties, rebates and fees)		52,832		38,095		
Payroll related		31,437		28,019		
Research related		7,635		7,500		
Other		4,027		4,773		
		0.7.004		=0.00=		
Total accrued expenses		95,931		78,387		
Total accounts payable and accrued expenses	\$	103,433	\$	85,382		

#### 7. Share Tracking Award Plans

We previously issued awards under the United Therapeutics Corporation Share Tracking Awards Plan, adopted in June 2008 (2008 STAP) and the United Therapeutics Corporation 2011 Share Tracking Awards Plan, adopted in March 2011 (2011 STAP). We refer to the 2008 STAP and the 2011 STAP collectively as the "STAP" and awards granted and/or outstanding under either of these plans as "STAP awards." STAP awards convey the right to receive in cash an amount equal to the appreciation of our common stock, which is measured as the increase in the closing price of our common stock between the dates of grant and exercise. STAP awards expire on the tenth anniversary of the date of grant, and in most cases they vest in equal increments on each anniversary of the grant date over a four-year period. The STAP liability includes vested awards and awards that are expected to vest. We recognize expense for awards that are expected to vest during the vesting period. We discontinued the issuance of STAP awards on June 26, 2015, when our shareholders approved the United Therapeutics Corporation 2015 Stock Incentive Plan (the 2015 Plan), a broad-based stock incentive plan enabling us to grant stock options and other forms of equity compensation to our employees. See Note 11 Stockholders' Equity to these consolidated financial statements for information on the 2015 Plan.

The aggregate balance of the STAP liability was \$354.8 million and \$322.7 million at December 31, 2015 and 2014, respectively, of which \$80.2 million and \$40.6 million, respectively, has been classified as

#### Table of Contents

#### UNITED THERAPEUTICS CORPORATION

#### **Notes to Consolidated Financial Statements (Continued)**

#### 7. Share Tracking Award Plans (Continued)

non-current liabilities under the caption "Other liabilities" on our consolidated balance sheets based on their vesting terms.

Estimating the fair value of STAP awards requires the use of certain inputs that can materially impact the determination of fair value and the amount of compensation expense (benefit) we recognize. Inputs used in estimating fair value include the price of our common stock, the expected volatility of the price of our common stock, the risk-free interest rate, the expected term of STAP awards, the expected forfeiture rate and the expected dividend yield. The fair value of the STAP awards is measured each financial reporting period because the awards are settled in cash.

A description of the key inputs, requiring estimates, used in determining the fair value of the awards is provided below:

Expected volatility Volatility is a measure of the amount the price of our common stock has fluctuated (historical volatility) or is expected to fluctuate (expected volatility) during a period. We use historical volatility based on weekly price observations of our common stock during the period immediately preceding an award that is equal to its expected term up to a maximum period of five years. We believe the volatility in the price of our common stock over the preceding five years generally provides a reliable projection of future long-term volatility.

Risk-free interest rate The risk-free interest rate is the average interest rate consistent with the yield available on a U.S. Treasury note with a term equal to the expected term of an award.

Expected term The expected term reflects the estimated time period we expect an award to remain outstanding. For the years ended December 31, 2015 and 2014, we used historical data to develop this input. Prior to 2014, we applied the simplified method to develop an estimate of the expected term. The change in methodologies for calculating the expected term of an award did not have a significant impact to our consolidated financial statements.

Expected forfeiture rate The expected forfeiture rate is an estimated percentage of awards granted that are expected to be forfeited or canceled on an annual basis prior to becoming fully vested. We derive our estimate based on historical forfeiture experience for similar classes of employees.

Expected dividend yield We do not pay cash dividends on our common stock and do not expect to do so in the future. Therefore, the dividend yield is zero.

The table below presents the assumptions used to measure the fair value of STAP Awards:

As of Decei	mber 31,
-------------	----------

	2015	2014	2013
Expected volatility	35.3%	34.0%	32.7%
Risk-free interest rate	1.4%	1.3%	1.1%
Expected term of awards (in years)	3.4	4.0	3.9
Expected forfeiture rate	8.8%	9.3%	10.1%
Expected dividend yield	0.0%	0.0%	0.0%
			F-24

# UNITED THERAPEUTICS CORPORATION

## **Notes to Consolidated Financial Statements (Continued)**

### 7. Share Tracking Award Plans (Continued)

A summary of the status and activity of the STAP is presented below:

	Number of Awards	Weighted- Average Exercise Price		Weighted Average Remaining Contractual Term (Years)		Aggregate Intrinsic Value (in 000s)	
Outstanding at January 1, 2015	7,716,424	\$	62.59				
Granted	1,655,388		159.68				
Exercised	(2,281,711)		56.71				
Forfeited	(244,938)		95.37				
Outstanding at December 31, 2015	6,845,163	\$	86.86	7.3	\$	487,010	
Exercisable at December 31, 2015	2,115,571	\$	67.79	6.1	\$	188,683	
Expected to vest at December 31, 2015	4,306,092	\$	95.34	7.9	\$	271,767	

The weighted average grant-date fair value of STAP awards granted during the years ended December 31, 2015, 2014 and 2013 was \$58.52, \$33.82 and \$24.78, respectively.

Share-based compensation expense recognized in connection with the STAP is as follows (in thousands):

	Year Ended December 31,						
	2015		2014		2013		
Research and development	\$ 87,372	\$	72,269	\$	134,355		
Selling, general and administrative	178,100		82,937		143,407		
Cost of product sales	8,706		4,283		6,124		
Share-based compensation expense before taxes	274,178		159,489		283,886		
Related income tax benefit	(103,431)		(56,560)		(106,693)		
Share-based compensation expense, net of taxes	\$ 170,747	\$	102,929	\$	177,193		
r r	, .		- ,-	•	,		
Share-based compensation capitalized as part of inventory	\$ 7,063	\$	2,027	\$	1,593		

Cash paid to settle STAP exercises during the years ended December 31, 2015, 2014 and 2013 was \$248.8 million, \$144.1 million, and \$55.9 million, respectively.

### 8. Debt

Unsecured Revolving Credit Facility

In January 2016, we entered into a Credit Agreement (the 2016 Credit Agreement) with Wells Fargo Bank, National Association (Wells Fargo), as administrative agent and a swingline lender, and various other lender parties, providing for an unsecured revolving credit facility of up to \$1.0 billion (the Revolving Facility), which is available to refinance certain of our existing indebtedness and/or for working capital and other general corporate purposes. The Revolving Facility will mature five years after the closing date of the 2016 Credit Agreement, subject to the lenders' ability to extend the

#### Table of Contents

#### UNITED THERAPEUTICS CORPORATION

#### **Notes to Consolidated Financial Statements (Continued)**

#### 8. Debt (Continued)

maturity date by one year if we request such an extension in accordance with the terms of the 2016 Credit Agreement.

At our option, amounts borrowed under the Revolving Facility will bear interest at either the LIBOR rate or a fluctuating base rate, in each case, plus an applicable margin determined on a quarterly basis based on our consolidated ratio of total indebtedness to EBITDA (as calculated in accordance with the 2016 Credit Agreement).

The 2016 Credit Agreement contains customary events of default and customary affirmative and negative covenants. As of January 29, 2016, we were in compliance with such covenants and we had not drawn any amounts on the Revolving Facility. In addition, Lung Biotechnology PBC is our only subsidiary that guarantees our obligations under the 2016 Credit Agreement though, from time to time, one or more of our other subsidiaries may be required to guarantee such obligations.

Secured Line of Credit

In September 2013, we entered into a credit agreement (the 2013 Credit Agreement) with Wells Fargo Bank, National Association (Wells Fargo) providing us a \$75.0 million revolving loan facility. In July 2015, we amended the credit agreement solely to extend its maturity to September 30, 2017. At our option, amounts borrowed under the 2013 Credit Agreement bore interest at either the one-month LIBOR rate plus a 0.50 percent margin, or a fluctuating base rate excluding any margin. In addition, we were subject to a monthly commitment fee of 0.06 percent per annum on the average daily unused balance of the facility. Amounts borrowed under the 2013 Credit Agreement were secured by certain of our marketable investments. As of December 31, 2015, we had no outstanding balance on the facility. In January 2016, we terminated and repaid in full all obligations under the 2013 Credit Agreement when we entered into the 2016 Credit Agreement.

Convertible Notes Due 2016

In October 2011, we issued \$250.0 million in aggregate principal value 1.0 percent Convertible Senior Notes due September 15, 2016 (Convertible Notes). The Convertible Notes are unsecured, unsubordinated debt obligations that rank equally with all of our other unsecured and unsubordinated indebtedness. We pay interest semi-annually on March 15 and September 15 of each year. The initial conversion price is \$47.69 per share and the number of underlying shares used to determine the aggregate consideration upon conversion is approximately 5.2 million shares.

Conversion can occur: (1) any time after June 15, 2016; (2) during any calendar quarter that follows a calendar quarter in which the price of our common stock exceeds 130 percent of the conversion price for at least 20 days during the 30 consecutive trading-day period ending on the last trading day of the quarter; (3) during the ten consecutive trading-day period following any five consecutive trading-day period in which the trading price of the Convertible Notes is less than 95 percent of the closing price of our common stock multiplied by the then-current number of shares underlying the Convertible Notes; (4) upon specified distributions to our shareholders; (5) in connection with certain corporate transactions; or (6) in the event that our common stock ceases to be listed on the NASDAQ Global Select Market, the NASDAQ Global Market or the New York Stock Exchange, or any of their respective successors. The closing price of our common stock exceeded 130 percent of the conversion price of the Convertible Notes for more than 20 trading days during the 30 consecutive trading day period ended December 31, 2015. Consequently, the Convertible Notes are

#### Table of Contents

## UNITED THERAPEUTICS CORPORATION

#### **Notes to Consolidated Financial Statements (Continued)**

#### 8. Debt (Continued)

convertible at the election of their holders. As the Convertible Notes have a maturity date of September 15, 2016, they are classified as a current liability on our consolidated balance sheet at December 31, 2015.

At December 31, 2015, the aggregate conversion value of the Convertible Notes exceeded their par value by \$12.8 million using a conversion price of \$156.61, the closing price of our common stock on December 31, 2015.

Upon conversion, holders of our Convertible Notes are entitled to receive: (1) cash equal to the lesser of the par value of the notes or the conversion value (the number of shares underlying the Convertible Notes multiplied by the then current conversion price per share); and (2) to the extent the conversion value exceeds the par value of the notes, shares of our common stock. In the event of a change in control, as defined in the indenture under which the Convertible Notes have been issued, holders can require us to purchase all or a portion of their Convertible Notes for 100 percent of the notes' par value plus any accrued and unpaid interest.

During the year ended December 31, 2015, we settled conversion requests representing \$133.2 million in principal value of our Convertible Notes. We paid \$133.2 million in principal and issued 2.0 million shares of our common stock during the settlement process. We received 2.0 million shares of our common stock under our convertible note hedge (discussed below under *Convertible Note Hedge and Warrant Transactions*) from Deutsche Bank AG London (DB London) which we placed into our treasury stock account. We recognized a \$3.7 million extinguishment loss with the settlement of these conversions. As of December 31, 2015, 117,000 shares of our common stock could be issued upon future conversions of our outstanding Convertible Notes.

The terms of the Convertible Notes provide for settlement wholly or partially in cash. Consequently, we are required to account for their liability and equity components separately so that the subsequent recognition of interest expense reflects our non-convertible borrowing rate. Accordingly, as of the date of issuance, we estimated the fair value of the Convertible Notes without consideration of the conversion option (Liability Component). The excess of the proceeds received over the estimated fair value of the Liability Component totaling \$57.9 million has been recorded as the conversion option (Equity Component) and a corresponding offset has been recognized as a discount to the Convertible Notes to reduce their net carrying value. A portion of the Equity Component equal to the unamortized discount as of December 31, 2015 has been reclassified to temporary equity because one of the contingent conversion criteria had been met at December 31, 2015, as disclosed above. Refer to Note 10 *Temporary Equity*. We are amortizing the discount over the five-year period ending September 15, 2016 (the expected life of the Liability Component) using the effective interest method and an effective rate of interest of 6.7 percent, which corresponded to our estimated non-convertible borrowing rate at the date of issuance.

Interest expense incurred in connection with our convertible notes consisted of the following (in thousands):

	Year Ended December 31,								
	2015					2013			
Contractual coupon rate of interest	\$	404	\$	2,151	\$	2,500			
Discount amortization		3,020		11,057		11,178			
Interest expense convertible notes	\$	3,424	\$	13,208	\$	13,678			

#### Table of Contents

#### UNITED THERAPEUTICS CORPORATION

#### **Notes to Consolidated Financial Statements (Continued)**

#### 8. Debt (Continued)

The carrying value of our convertible notes consisted of the following (in thousands):

	As of December 31,			
		2015		2014
Principal balance	\$	5,600	\$	138,750
Discount, net of accumulated amortization of \$1,085 and \$19,819		(213)		(12,336)
Carrying amount	\$	5,387	\$	126,414

#### Convertible Note Hedge and Warrant Transactions

In connection with the issuance of our Convertible Notes, we entered into separate convertible note hedge and warrant transactions with DB London to reduce the potentially dilutive impact of the conversion of our convertible notes. Pursuant to the convertible note hedge, we purchased call options to acquire up to approximately 5.2 million shares of our common stock with a strike price of \$47.69. The call options become exercisable upon any conversions and the maturity of the Convertible Notes, and will terminate upon the maturity of the Convertible Notes or the first day the Convertible Notes are no longer outstanding, whichever occurs first. The call options will offset on a share for share basis, any shares of our common stock that we issue upon any conversion or at the maturity of our Convertible Notes. As of December 31, 2015, approximately 117,000 shares of our common stock remained under the call options after the settlement of \$133.2 million of conversion requests during the year ended December 31, 2015. We also sold DB London warrants to acquire up to approximately 5.2 million shares of our common stock with a strike price of \$67.56. The warrants will expire incrementally on a series of expiration dates subsequent to the maturity date of our Convertible Notes. Both the convertible note hedge and warrant transactions will be settled on a net-share basis. To the extent that the price of our common stock exceeds the strike price of the warrants on any or all of the series of related incremental expiration dates, we will be required to issue shares of our common stock to DB London.

Mortgage Financing Wells Fargo Bank

In December 2010, we entered into a Credit Agreement with Wells Fargo and Bank of America, N.A., pursuant to which we obtained a \$70.0 million mortgage loan (the 2010 Credit Agreement). The 2010 Credit Agreement matured in December 2014 and we repaid the outstanding \$66.5 million principal balance in full.

Interest Expense

Details of interest expense presented on our consolidated statements of operations are as follows (in thousands):

	Year Ended December 31,									
		2015			2013					
Interest expense	\$	4,735	\$	17,592	\$	18,117				
Less: interest capitalized						(59)				
Total interest expense	\$	4,735	\$	17,592	\$	18,058				

#### UNITED THERAPEUTICS CORPORATION

#### **Notes to Consolidated Financial Statements (Continued)**

#### 9. Commitments and Contingencies

Operating Leases

We lease facilities and equipment under operating lease arrangements that have terms expiring at various dates through 2020. Certain lease arrangements include renewal options and escalation clauses. In addition, various lease agreements to which we are party require that we comply with certain customary covenants throughout the term of these leases. If we are unable to comply with these covenants and cannot reach a satisfactory resolution in the event of noncompliance, these agreements could terminate.

Future minimum lease payments under non-cancelable operating leases as of December 31, 2015 are as follows (in thousands):

Year Ending December 31,	
2016	\$ 3,716
2017	3,447
2018	2,636
2019	498
2020	237
Thereafter	
Total	\$ 10,534

Total rent expense was \$3.8 million, \$3.6 million and \$3.5 million for the years ended December 31, 2015, 2014 and 2013, respectively.

Milestone Payments

We are party to certain license agreements as described in Note 15 Assignment and License Agreements and acquisition agreements. Generally, these agreements require that we make milestone payments in cash upon the achievement of certain product development and commercialization goals and payments of royalties upon commercial sales.

Future milestone payments based on our estimates of the timing and probability of achieving milestones specified under these arrangements are as follows (in thousands):

Year Ending December 31,	(1)
2016	\$ 6,136
2017	4,640
2018	3,705
2019	9,711
2020	1,759
Thereafter	7,070
Total	\$ 33,021

<sup>(1)</sup> The amounts and timing of future milestone payments may vary depending on when related milestones will be attained, if at all.

#### UNITED THERAPEUTICS CORPORATION

#### **Notes to Consolidated Financial Statements (Continued)**

#### 10. Temporary Equity

Temporary equity includes securities that: (1) have redemption features that are outside our control; (2) are not classified as an asset or liability; (3) are excluded from permanent stockholders' equity; and (4) are not mandatorily redeemable. Amounts included in temporary equity relate to securities that are redeemable at a fixed or determinable price.

Components comprising the carrying value of temporary equity include the following (in thousands):

	Dece	As of mber 31, 2015	As of December 31, 2014		
Reclassification of Equity Component <sup>(1)</sup>	\$	213	\$	12,336	
Common stock subject to repurchase <sup>(2)</sup>		10,882		10,882	
Total	\$	11.095	\$	23,218	

- (1)

  Represents the reclassification of the Equity Component equal to the unamortized debt discount of our Convertible Notes as of December 31, 2015 and 2014, respectively, from additional paid-in capital to temporary equity. Our Convertible Notes were convertible at the election of their holders as noted above in Note 8 *Debt Convertible Notes Due 2016*.
- In connection with our license agreement with Toray Industries Inc. (Toray), we issued 200,000 shares of our common stock (which have since split into 400,000 shares) to Toray in 2007, and provided Toray the right to require us to repurchase the shares at a price of \$27.21 per share.

#### 11. Stockholders' Equity

Equity Incentive Plans

As of December 31, 2015, we have two shareholder-approved equity incentive plans: the United Therapeutics Corporation Amended and Restated Equity Incentive Plan (the 1999 Plan) and the United Therapeutics Corporation 2015 Stock Incentive Plan (the 2015 Plan). Although the terms of the 1999 Plan and the 2015 Plan contemplate a variety of awards, to date all awards granted under these plans have been in the form of stock options. The 2015 Plan was approved by our shareholders in June 2015 and provides for the issuance of up to 6,150,000 shares of our common stock pursuant to awards granted under the 2015 Plan. During the year ended December 31, 2015, we granted zero stock options under the 1999 plan and 172,250 stock options under the 2015 Plan. During the year ended December 31, 2014, we granted 723,869 stock options under the 1999 Plan. No further awards will be granted under the 1999 Plan.

Employee Stock Options

We estimate the fair value of stock options using the Black-Scholes-Merton valuation model. Option-pricing models, including the Black-Scholes-Merton model, require the use of judgment and subjective assumptions that can materially impact the estimation of fair value and share-based compensation.

#### Table of Contents

## UNITED THERAPEUTICS CORPORATION

#### **Notes to Consolidated Financial Statements (Continued)**

#### 11. Stockholders' Equity (Continued)

Inputs included in estimating the fair value of a stock option include the price of our common stock, the expected volatility of our common stock, risk-free interest rate, the expected term of stock option awards, expected forfeiture rate and the expected dividend yield.

A description of the key inputs, requiring estimates, used in determining the fair value of stock options is provided below:

Expected volatility Volatility is a measure of the amount the price of our common stock has fluctuated (historical volatility) or is expected to fluctuate (expected volatility) during a period. We use historical volatility based on weekly price observations of our common stock during the period immediately preceding a stock option grant that is equal to the expected term of the grant (up to a maximum of five years). We believe the volatility of the price of our common stock measured over the preceding five years provides a reliable projection of future long-term volatility.

Risk-free interest rate The risk-free interest rate is the average interest rate consistent with the yield available on a U.S. Treasury note with a term equal to the expected term of a given stock option grant.

Expected term The expected term reflects the estimated time period we expect an option grant to remain outstanding. We use historical data to develop this input.

Expected forfeiture rate The expected forfeiture rate is the estimated percentage of options granted that are expected to be forfeited or canceled on an annual basis prior to becoming fully vested. We derive our estimate based on historical forfeiture experience for similar classes of employees.

Expected dividend yield We do not pay dividends on our common stock and do not expect to do so in the future. Therefore, the dividend yield is assumed to be zero.

The following weighted-average assumptions were used in estimating the fair value of stock options granted to employees:

	Year Ei Decembe	
	2015	2014
Expected volatility	33.1%	32.6%
Risk-free interest rate	2.0%	1.7%
Expected term of options (in years)	5.8	5.0
Expected forfeiture rate	1.5%	0.0%
Expected dividend yield	0.0%	0.0%
		F-31

#### Table of Contents

## UNITED THERAPEUTICS CORPORATION

#### **Notes to Consolidated Financial Statements (Continued)**

## 11. Stockholders' Equity (Continued)

A summary of the status and activity of employee stock options is presented below:

Options	Weighted- Average Exercise Price		Average Remaining Contractual Term (in Years)		Aggregate Intrinsic Value (in 000s)
4,054,771	\$	76.83			
172,250		173.25			
(984,583)		39.90			
3,242,438	\$	93.17	6.6	\$	208,643
3,070,188	\$	88.68	6.4	\$	208,559
169,737	\$	173.53	9.5	\$	73
	4,054,771 172,250 (984,583) 3,242,438 3,070,188	Options 4,054,771 \$ 172,250 (984,583) 3,242,438 \$ 3,070,188 \$	Average Exercise Price 4,054,771 \$ 76.83 172,250 173.25 (984,583) 39.90 3,242,438 \$ 93.17 3,070,188 \$ 88.68	Weighted-Average Exercise Price (in Years) 4,054,771 \$ 76.83 172,250 173.25 (984,583) 39.90  3,242,438 \$ 93.17 6.6  3,070,188 \$ 88.68 6.4	Weighted-Average   Exercise   Price   (in Years)   (in

The weighted average fair value of an employee stock option granted during each of the years in the three-year period ended December 31, 2015, was \$60.70, \$40.70 and \$36.10, respectively. The total fair value of employee stock options that vested for each of the years in the three-year period ended December 31, 2015 was \$0.0 million, \$29.5 million and \$36.1 million, respectively.

Total share-based compensation expense relating to employee stock options is as follows (in thousands):

	Year Ended December 31,								
		2015		2014		2013			
Research and development	\$	3	\$		\$				
Selling, general and administrative		4,894		29,460		36,097			
Related income tax benefit		(1,847)		(10,429)		(13,566)			
Share-based compensation expense, net of taxes	\$	3,050	\$	19,031	\$	22,531			

As of December 31, 2015, the unrecognized compensation cost was \$5.4 million. As of December 31, 2014, all employee stock options were fully vested; consequently, there were no amounts of unrecognized compensation cost remaining.

Employee and non-employee stock option exercise data is summarized below (dollars in thousands):

Year Ended December 31,						
2015	2014	2013				

Number of options exercised	985,583		1,462,369	876,115
Cash received from options exercised	\$ 39,311	\$	50,168	\$ 26,619
Total intrinsic value of options exercised	\$ 120,319	\$	108,425	\$ 37,530
Tax benefits realized from options exercised	\$ 37,426	\$	30,845	\$ 9,299
		F-3	2	

#### UNITED THERAPEUTICS CORPORATION

#### **Notes to Consolidated Financial Statements (Continued)**

#### 11. Stockholders' Equity (Continued)

Employee Stock Purchase Plan

In June 2012, our shareholders approved the United Therapeutics Corporation Employee Stock Purchase Plan (ESPP), which has been structured to comply with Section 423 of the Internal Revenue Code. The ESPP provides eligible employees the right to purchase shares of our common stock at a discount through elective accumulated payroll deductions at the end of each offering period. Offering periods, which began in September 2012, occur in consecutive six-month periods commencing on September 5th and March 5th of each year. Eligible employees may contribute up to 15 percent of their base salary, subject to certain annual limitations as defined in the ESPP. The purchase price of the shares is equal to the lower of 85 percent of the closing price of our common stock on either the first or last trading day of a given offering period. In addition, the ESPP provides that no eligible employee may purchase more than 4,000 shares during any offering period. The ESPP has a 20-year term and limits the aggregate number of shares that can be issued to 3.0 million.

We estimate the fair value of the option to purchase shares of our common stock under the ESPP using the same methodology that we employ in valuing our stock options and STAP awards.

#### Earnings Per Common Share

Basic earnings per share is computed by dividing net income by the weighted average number of shares of common stock outstanding during the period. Diluted earnings per share is computed by dividing net income by the weighted average number of shares of common stock outstanding during the period, adjusted for the potential dilutive effect of other securities if such securities were converted or exercised.

The components of basic and diluted earnings per share comprised the following (in thousands, except per share amounts):

	Year Ended December 31,					
		2015		2014		2013
Numerator:						
Net income	\$	651,639	\$	340,074	\$	174,560
Denominator:						
Weighted average outstanding shares basic		46,000		48,176		50,076
Effect of dilutive securities <sup>(1)</sup> :						
Convertible notes		915		2,630		1,736
Warrants		3,009		1,910		276
Stock options and employee stock purchase plan		1,297		1,439		1,143
Weighted average shares diluted		51,221		54,155		53,231
Earnings per common share:						
Basic	\$	14.17	\$	7.06	\$	3.49
Diluted	\$	12.72	\$	6.28	\$	3.28

Stock or	tions and warrants excluded from calculation(2)	3,800	9,273	11,210
(1)	Calculated using the treasury stock method.			
	Calculated using the treasury stock method.			
		F-33		

#### Table of Contents

#### UNITED THERAPEUTICS CORPORATION

#### **Notes to Consolidated Financial Statements (Continued)**

#### 11. Stockholders' Equity (Continued)

(2)

Certain stock options and warrants have been excluded from the computation of diluted earnings per share because their impact would be anti-dilutive. Under our convertible note hedge agreement, we are entitled to receive shares required to be issued to investors upon conversion of our Convertible Notes. Since related shares used to compute dilutive earnings per share would be anti-dilutive, they have been excluded from the calculation above.

Share Repurchases

In June 2014, our Board of Directors authorized the repurchase of up to \$500.0 million of our common stock. This program became effective on August 1, 2014, and remained open for one year. During the years ended December 31, 2015, and 2014, we repurchased 2,368,645 and 887,114 shares of our common stock, respectively, at an aggregate cost of \$394.5 million and \$105.5 million, respectively, under this repurchase program. We completed this repurchase program during the quarter ended September 30, 2015.

In October 2015, our Board of Directors authorized a new program for the repurchase of up to \$500.0 million of our common stock in open or privately negotiated transactions, at our discretion. This program is effective from January 1, 2016 through December 31, 2016. During the month ended January 31, 2016, we repurchased approximately 280,000 shares of our common stock at an aggregate cost of \$37.8 million.

Shareholder Rights Plan

In June 2008, we entered into an Amended and Restated Rights Agreement with The Bank of New York as Rights Agent (the Plan), which amended and restated our original Rights Agreement dated December 17, 2000. The Plan, as amended and restated, extended the expiration date of the Preferred Share Purchase Rights (Rights) from December 29, 2010 to June 26, 2018, and increased the purchase price of each Right from \$64.75 to \$400.00, respectively. Each Right entitles holders to purchase one one-thousandth of a share of our Series A Junior Participating Preferred Stock. Rights are exercisable only upon our acquisition by another company, or commencement of a tender offer that would result in ownership of 15 percent or more of the outstanding shares of our voting stock by a person or group (as defined under the Plan) without our prior express written consent. As of December 31, 2015, we have not issued any shares of our Series A Preferred Stock.

## UNITED THERAPEUTICS CORPORATION

#### **Notes to Consolidated Financial Statements (Continued)**

## 12. Accumulated Other Comprehensive Loss

The following table includes changes in accumulated other comprehensive (loss) income by component, net of tax (in thousands):

	 ed Benefit on Plan <sup>(1)</sup>	Foreign Currency Translation Losses	Unrealized Gains and (Losses) on Available-for- Sale Securities	Total
Balance, January 1, 2015	\$ (6,957)	\$ (9,858)	\$ 81	\$ (16,734)
Other comprehensive income (loss) before reclassifications	826	(5,296)	(74)	(4,544)
Amounts reclassified from accumulated other comprehensive gain	877			877
Net current-period other comprehensive income (loss)	1,703	(5,296)	(74)	(3,667)
Balance, December 31, 2015	\$ (5,254)	\$ (15,154)	\$ 7	\$ (20.401)

### 13. Income Taxes

Components of income tax expense (benefit) consist of the following (in thousands):

	Year Ended December 31,						
		2015		2014		2013	
Current:							
Federal	\$	320,726	\$	137,993	\$	120,030	
State		33,978		19,051		20,099	
Foreign		806		1,252		2,164	
Total current		355,510		158,296		142,293	
Deferred							
Federal		(2,846)		(2,945)		(37,713)	
State		7,279		463		(9,059)	
Foreign		194		(225)		(1,055)	
_							
Total deferred		4,627		(2,707)		(47,827)	

Other non-current			
Federal	29,678	27,115	7,797
State	2,990	2,383	1,907
Foreign	(7)	19	173

<sup>(1)</sup> Refer to Note 14 *Employee Benefit Plans Supplemental Executive Retirement Plan*, which identifies the captions within our consolidated statement of operations where reclassification adjustments were recognized and their associated tax impact.

Total other	32,661	29,517	9,877
Total income tax expense	\$ 392,798	\$ 185,106	\$ 104,343
			F-35

#### UNITED THERAPEUTICS CORPORATION

#### **Notes to Consolidated Financial Statements (Continued)**

#### 13. Income Taxes (Continued)

Presented below is a reconciliation of income taxes computed at the statutory federal tax rate to income tax expense as reported (in thousands):

	Year Ended December 31,					
		2015		2014		2013
Federal tax provision computed at 35%	\$	365,476	\$	183,813	\$	97,616
State tax provision, net of federal tax provision		28,760		12,865		8,320
General business credits		(6,904)		(12,195)		(13,346)
Incentive stock option expense				(181)		(304)
Section 199 deduction		(21,774)		(11,735)		(10,861)
Nondeductible compensation expense		29,280		13,000		22,813
Nondeductible expenses		(2,040)		(461)		105
Total income tax expense	\$	392,798	\$	185,106	\$	104,343

Components of the net deferred tax asset are as follows (in thousands):

	As of December 31,		ber 31,
		2015	2014
Deferred tax assets:			
General business credits	\$	\$	2,186
Impairment losses on investments		294	291
License fees capitalized for tax purposes		53,439	61,770
Nonqualified stock options		37,424	42,697
SERP		17,141	17,478
STAP awards		95,152	86,414
Other		27,074	29,086
Total deferred tax assets		230,524	239,922
Deferred tax liabilities:			
Plant and equipment principally due to differences in depreciation		(26,461)	(30,758)
Other		(7,995)	(7,854)
Net deferred tax asset before valuation allowance		196,068	201,310
Valuation allowance		(3,392)	(2,981)
Net deferred tax assets	\$	192,676 \$	198,329

Deferred tax assets are reduced by a valuation allowance when, in our judgment, it is more likely than not that a portion or all of the deferred tax assets will not be realized. In evaluating our ability to realize deferred tax assets, we consider all available positive and negative evidence. Accordingly, we consider past operating results, forecasts of earnings and taxable income, the reversal of temporary differences and any prudent and feasible tax planning strategies. Future increases in the valuation allowance would result in a corresponding charge to earnings in the period such a determination is made. Conversely, future reductions to the valuation allowance would result in the recognition of a tax benefit in the period we conclude a reduction is warranted.

#### UNITED THERAPEUTICS CORPORATION

#### **Notes to Consolidated Financial Statements (Continued)**

#### 13. Income Taxes (Continued)

A reconciliation of the beginning and ending balances of unrecognized tax benefits for the years indicated is as follows (in thousands):

Unrecognized tax benefits at January 1, 2013	\$ 1,511
Gross increases tax positions in prior period	1,325
Unrecognized tax benefits at December 31, 2013	\$ 2,836
Unrecognized tax benefits at January 1, 2014	\$ 2,836
Gross increases tax positions in prior period	28
Gross decreases tax positions in prior period	(1,419)
Unrecognized tax benefits at December 31, 2014	\$ 1,445
Unrecognized tax benefits at January 1, 2015	\$ 1,445
Lapse of statute of limitations	(945)
Unrecognized tax benefits at December 31, 2015	\$ 500

Included in unrecognized tax benefits at December 31, 2015, 2014 and 2013, is \$342,000, \$1.0 million, and \$2.4 million, respectively, of tax benefits that, if recognized, would impact the effective tax rate. As of December 31, 2015 and 2014, we accrued zero and \$28,000, respectively, in interest expense relating to uncertain state tax positions.

We are subject to federal and state taxation in the United States and various foreign jurisdictions. Currently, our 2014, 2013, 2012 and 2011 tax years are subject to examination by the IRS and by state taxing authorities. We are unaware of any positions for which it is reasonably possible that the total amounts of unrecognized tax benefits will significantly increase or decrease within the next twelve months.

## 14. Employee Benefit Plans

Supplemental Executive Retirement Plan

We maintain the United Therapeutics Corporation Supplemental Executive Retirement Plan (SERP) to provide retirement benefits to certain senior members of our management team.

Participants who retire at age 60 or older are eligible to receive either monthly payments or a lump sum payment based on an average of their total gross base salary over the last 36 months of active employment, subject to certain adjustments. Related benefit payments commence on the first day of the sixth month after retirement. Participants who elect to receive monthly payments will continue payments through the remainder of their life. Alternatively, participants who elect to receive a lump sum distribution will receive a payment equal to the present value of the estimated monthly payments that would have been received upon retirement. As of December 31, 2015 and 2014, all SERP participants had elected to receive a lump sum distribution. Participants who terminate employment for any reason other than death, disability, or change in control prior to age 60 will not be entitled to receive any benefits under the SERP.

We recognize the unfunded balance of the SERP as a liability on our consolidated balance sheets. Since we do not fund the SERP, the liability is equal to the projected benefit obligation as measured at the end of each fiscal year. Expenses related to the SERP are reported under the captions, "Research

F-37

## UNITED THERAPEUTICS CORPORATION

#### **Notes to Consolidated Financial Statements (Continued)**

#### 14. Employee Benefit Plans (Continued)

and development expense" and "Selling, general and administrative expense" in the accompanying consolidated statements of operations.

A reconciliation of the beginning and ending balances of the projected benefit obligation is presented below (in thousands):

	Year Ended December 31,			
		2015		2014
Projected benefit obligation at the beginning of the year	\$	57,955	\$	51,034
Service cost		3,518		5,517
Interest cost		1,836		2,367
Plan amendments				3,862
Benefits paid		(7,117)		
Actuarial gain		(1,379)		(4,825)
Projected benefit obligation at the end of the year	\$	54,813	\$	57,955

Fair value of plan assets at the end of the year

Unfunded at end of the vear <sup>(1)</sup>	\$	54.813	\$	57.955	
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(1)
At December 31, 2015, the aggregate balance of the SERP liability was \$54.8 million, of which \$14.7 million, representing the benefit obligation due for participants who are currently eligible to retire, has been classified as current liabilities under the caption "Other current liabilities" on our consolidated balance sheets.

The accumulated benefit obligation, a measure that does not consider future increases in participants' salaries, was \$42.3 million and \$43.5 million at December 31, 2015 and 2014, respectively.

Future estimated benefit payments, based on current assumptions, including election of lump-sum distributions and expected future service, are as follows (in thousands):

Year Ended December 31,	
2016	\$ 14,651
2017	
2018	
2019	4,580
2020	
2021 - 2025	51,836
Total	\$ 71,067

## Table of Contents

## UNITED THERAPEUTICS CORPORATION

#### **Notes to Consolidated Financial Statements (Continued)**

## 14. Employee Benefit Plans (Continued)

The following weighted-average assumptions were used to measure the SERP obligation:

	Year Ei	Year Ended			
	Decembe	er 31,			
	2015	2014			
Discount Rate	3.82%	3.64%			

Salary Increases 4.00% 5.00%

The components of net periodic pension cost recognized on our consolidated statement of operations consist of the following (in thousands):

Voor	Ended	December	31
i eai	Liiueu	December	ы.

	2015	2014	2013
Service cost	\$ 3,518	\$ 5,517	\$ 5,406
Interest cost	1,836	2,367	1,584
Amortization of prior service cost	1,234	1,234	827
Amortization of net actuarial loss	160	210	794
Total	\$ 6,748	\$ 9.328	\$ 8.611

Reclassification adjustments related to the SERP from accumulated other comprehensive loss to the statement of operations by line item and the tax impact of these reclassifications is presented below (in thousands):

Components Reclassified from Accumulated Other Comprehensive Loss <sup>(1)</sup>	Decei	as of nber 31, 1015	As of December 31, 2014		
Prior service cost:					
Research and development	\$	408	\$	408	
Selling, general and administrative		826		826	
Total		1,234		1,234	
Amortization of net actuarial loss:					
Research and development				69	
Selling, general and administrative		160		141	
Total		160		210	
Total prior service cost and amortization of net actuarial loss		1,394		1,444	
Tax benefit		(517)		(540)	
Total, net of tax	\$	877	\$	904	

(1) Refer to Note 12 Accumulated Other Comprehensive Loss.

F-39

#### Table of Contents

#### UNITED THERAPEUTICS CORPORATION

#### **Notes to Consolidated Financial Statements (Continued)**

#### 14. Employee Benefit Plans (Continued)

Amounts relating to the SERP that have been recognized in other comprehensive gain (loss) are as follows (in thousands):

#### Year Ended December 31,

	2015	2014	2013
Net unrecognized actuarial gain	\$ 1,539 \$	5,035	\$ 3,956
Net unrecognized prior service cost (benefit)	1,234	(2,627)	827
Total	2,773	2,408	4,783
Tax benefit	(1,070)	(920)	(1,688)
Total, net of tax	\$ 1,703 \$	1,488	\$ 3,095

The table below presents amounts relating to the SERP included in accumulated other comprehensive loss that have not yet been recognized as a component of net periodic pension cost on our consolidated statements of operations (in thousands):

#### Year Ended December 31,

	2015	2014	2013
Net unrecognized actuarial loss	\$ 1,228	\$ 2,767	\$ 7,803
Net unrecognized prior service cost	7,093	8,326	5,698
Total	8,321	11,093	13,501
Tax benefit	(3,067)	(4,150)	(5,074)
Total, net of tax	\$ 5,254	\$ 6,943	\$ 8,427

Estimated amounts included in accumulated other comprehensive loss as of December 31, 2015 that are expected to be recognized as components of net periodic pension expense on our statement of operations for the year ended December 31, 2016 comprise the following (in thousands):

Amortization of prior service cost	\$ 1,234
Amortization of net actuarial loss	
Total	\$ 1,234

#### Employee Retirement Plan

We maintain a Section 401(k) Salary Reduction Plan which is open to all eligible full-time employees. Under the 401(k) Plan, eligible employees can make pre-tax contributions up to statutory limits. Currently, we make discretionary matching contributions to the 401(k) Plan equal to 40 percent of a participant's elected salary deferral. Matching contributions vest immediately for participants who have been employed for three years; otherwise, matching contributions vest annually, in one-third increments over a three-year period until the three-year

employment requirement has been met.

#### Table of Contents

## UNITED THERAPEUTICS CORPORATION

#### **Notes to Consolidated Financial Statements (Continued)**

#### 15. Assignment and License Agreements

#### GlaxoSmithKline plc

In 1997, GlaxoSmithKline plc (Glaxo) assigned to us patents and patent applications covering treprostinil for the treatment of PAH and congestive heart failure. Under the agreement, Glaxo was entitled to receive royalties on sales exceeding a specified threshold for a minimum period of ten years (or until expiration of the licensed patents) following the date of the first commercial sale of any initial product containing treprostinil. Pursuant to these terms, our royalty obligation ended in October 2014.

#### Supernus Pharmaceuticals, Inc.

In June 2006, we entered into an exclusive license agreement with Supernus Pharmaceuticals, Inc. (Supernus) for the use of certain technologies developed by Supernus in our Orenitram tablet. Under this agreement, we paid Supernus certain amounts upon the achievement of specified milestones based on the development and commercial launch of Orenitram for PAH, and we would be obligated to make additional milestone payments if we develop Orenitram for a second indication. Additionally, we will pay a single digit royalty under this agreement, based on net product sales of Orenitram. Royalties will be paid for approximately twelve years commencing with the first commercial sale, subject to adjustments. The royalties commenced in the second quarter of 2014 with the first sale of Orenitram.

#### Eli Lilly and Company

In November 2008, we acquired from Lilly exclusive rights to develop, market, promote and commercialize Adcirca for the treatment of pulmonary hypertension in the United States. In exchange for these license rights, we agreed to pay Lilly, among other fees, royalties of five percent of our net product sales of Adcirca as a pass through of Lilly's third-party royalty obligations for as long as Lilly is required to make such royalty payments. Pursuant to the terms of our license arrangement, Lilly manufactures Adcirca for us and distributes Adcirca via its wholesaler network in the same manner that it distributes its own pharmaceutical products. We purchase Adcirca from Lilly at a fixed manufacturing cost, which is adjusted by Lilly from time to time. The terms of this licensing arrangement will continue generally until the later of: (1) the expiration or lapse of the last to expire claim within a Lilly patent covering commercialization of Adcirca; or (2) the expiration of any government conferred exclusivity rights to Adcirca. In addition, at Lilly's discretion the license agreement may be terminated in the event that we undergo a change in control.

#### National Cancer Institute

In July 2010, we entered into a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute (NCI) of the United States National Institutes for Health (NIH) to collaborate on the late-stage development and regulatory approval process for Unituxin for children with high-risk neuroblastoma and patients with other forms of cancer. In lieu of a royalty payment to the NCI, we have an ongoing obligation to provide the NCI with Unituxin for its studies free of charge.

### Toray Industries, Inc.

In 2000, we entered into an agreement with Toray to obtain exclusive rights to develop and market beraprost, a chemically stable oral prostacyclin analogue, in a sustained release formulation in the United States and Canada for the treatment of all cardiovascular indications. In 2007, we amended the agreement to expand our rights to commercialize modified release formulations of beraprost, which

Table of Contents

## UNITED THERAPEUTICS CORPORATION

#### **Notes to Consolidated Financial Statements (Continued)**

#### 15. Assignment and License Agreements (Continued)

include esuberaprost. As part of the 2007 amendment, we issued 200,000 shares of our common stock (which have since split into 400,000 shares) to Toray with certain put rights. These put rights provide Toray the ability to request at its discretion that we repurchase these shares at a price of \$27.21 per share upon 30 days' prior written notice. Accordingly, we classified the value of the shares within temporary equity on our consolidated balance sheets. In the event that Toray requests that we repurchase these shares, we will reclassify the repurchase value of the stock as a liability until settlement. The 2007 amendment also provided for certain milestone payments during the development period and upon receipt of regulatory approval in the United States or the European Union.

In July 2011, we amended our license agreement with Toray. The amendment did not materially change the terms of our license agreement, except for a reduction in royalty rates in exchange for a total of \$50.0 million in equal, non-refundable payments to Toray over the five-year period ending in 2015. As of December 31, 2015, we have fulfilled this obligation to Toray.

#### Pluristem License Agreement

In June 2011, we entered into a license agreement with Pluristem Ltd. (Pluristem) for exclusive worldwide rights to develop and commercialize a cell-based product for the treatment of PAH using Pluristem's proprietary PLX cell technology. The agreement provided for additional milestone payments to Pluristem at various stages, as well as royalties on commercial sales. In December 2015, we terminated our licensing agreement with Pluristem and our development of the PLX program.

#### Medtronic Inc.

In 2009, we entered into an agreement with Medtronic, Inc. (Medtronic) providing us exclusive rights in the United States, the United Kingdom, Canada, France, Germany, Italy and Japan to develop Medtronic's proprietary intravascular infusion catheter to be used with its SynchroMed® II implantable infusion pump and related infusion system components (together referred to as the Remodulin Implantable System) in order to deliver Remodulin for the treatment of PAH. If this development program is successful, our agreement provides that, upon commercialization, we will purchase infusion pumps and supplies from Medtronic and will also pay a royalty to Medtronic based on net product sales of Remodulin for use in the Remodulin Implantable System within the exclusive territories, subject to certain adjustments specified in the agreement. The Remodulin Implantable System will be exclusive to Remodulin so long as we purchase a minimum percentage of our annual requirement for implantable pump systems from Medtronic. We will be solely responsible for all marketing and promotion of the Remodulin Implantable System for the delivery of Remodulin for the treatment of PAH in the exclusive territories.

### DEKA Research & Development Corp.

In December 2014, we entered into an exclusive agreement with DEKA Research & Development Corp. (DEKA) to develop a pre-filled, semi-disposable pump system for subcutaneous delivery of Remodulin. Under the terms of the agreement, we will fund the development costs related to the semi-disposable pump system and will pay product fees and a single-digit royalty to DEKA based on commercial sales of the system and the Remodulin sold for use with the system.

#### Table of Contents

#### UNITED THERAPEUTICS CORPORATION

#### **Notes to Consolidated Financial Statements (Continued)**

#### 15. Assignment and License Agreements (Continued)

#### Other

We are party to various other license agreements relating to therapies under development. These license agreements require us to make payments based on a percentage of sales, if we are successful in commercially developing these therapies, and may require other payments upon the achievement of certain milestones.

#### 16. Distribution Agreements

### U.S.-Based Specialty Distributors

We are party to separate distribution agreements for Remodulin, Tyvaso and Orenitram with two U.S.-based specialty pharmaceutical distributors. The distribution agreements are similar to one another, and generally have one-year terms that renew automatically for additional one-year periods, unless terminated earlier. The agreements contain contractual responsibilities relating to ordering specifications, inventory requirements and exchange rights. We also have agreements with these distributors to perform certain services for us on a fee-for-service basis. If any of our distribution agreements expire or terminate, we may be required under certain circumstances to repurchase any unsold inventory held by our distributors. In the second quarter of 2015, we entered into an exclusive distribution agreement with ASD Specialty Healthcare, Inc. (ASD), an affiliate of AmerisourceBergen Corporation, to distribute Unituxin in the United States. Under this Agreement, we sell Unituxin to ASD at a transfer price that we establish, and we pay ASD fees for services provided in connection with the distribution and support of Unituxin.

#### International Distributors

We currently sell Remodulin and Tyvaso internationally through various distributors. The financial terms and conditions relating to these distributor arrangements are structured in a manner substantially similar to those of our U.S. distribution agreements described above.

## 17. Segment Information

We currently operate as one operating segment. However, our chief operating decision makers regularly review net product sales, cost of product sales and gross profit data as a primary measure of performance for each of our five commercial products. We commenced sales of Orenitram and Unituxin during the second quarter of 2014 and third quarter of 2015, respectively.

#### UNITED THERAPEUTICS CORPORATION

#### **Notes to Consolidated Financial Statements (Continued)**

## 17. Segment Information (Continued)

Net product sales, cost of product sales and gross profit for each of our commercial products were as follows (in thousands):

Year Ended December 31, 2015	R	emodulin	Tyvaso	Adcirca	O	renitram	U	nituxin	Tota	ıl
Net product sales	\$	572,795	\$ 470,069	\$ 278,829	\$	118,434	\$	20,443 \$	1,46	0,570
Cost of product sales		12,373	23,925	16,504		12,569		3,665	6	9,036
Gross profit	\$	560,422	\$ 446,144	\$ 262,325	\$	105,865	\$	16,778 \$	1,39	1,534

Year Ended December 31, 2014						
Net product sales	\$	553,728 \$	463,067 \$	221,471 \$	41,267 \$	\$ 1,279,533
Cost of product sales		47,327	57,442	13,495	7,619	125,883
•						
C	φ	506 401 ¢	105 605 ¢	207.076 6	22 649 6	¢ 1.152.650
Gross profit	Ф	506,401 \$	403,023 \$	207,976 \$	33,648 \$	\$ 1,153,650

Year Ended December 31, 2013					
Net product sales	\$ 491,179 \$	438,793 \$	176,972 \$	\$ \$	1,106,944
Cost of product sales	59,314	60,831	10,982		131,127
Gross profit	\$ 431,865 \$	377,962 \$	165,990 \$	\$ \$	975,817

Geographic revenues are determined based on the country in which our customers (distributors) are located. Total revenues from external customers by geographic area are as follows (in thousands):

Year Ended December 31,	2015	2014	2013
United States	\$ 1,353,002	\$ 1,180,759	\$ 1,032,435
Rest-of-World <sup>(1)</sup>	112,759	107,760	84,549
Total <sup>(2)</sup>	\$ 1,465,761	\$ 1,288,519	\$ 1,116,984

(2)

<sup>(1)</sup> Primarily Europe.

Total includes other revenue of \$5.2 million, \$9.0 million and \$10.0 million for the years ended December 31, 2015, 2014 and 2013, respectively.

For the years ended December 31, 2015, 2014 and 2013, net product sales to Accredo Health Group, Inc. comprised 55 percent, 58 percent and 57 percent, respectively of total revenues.

Long-lived assets (property, plant and equipment) located by geographic area are as follows (in thousands):

Year Ended December 31,	2015	2014
United States	\$ 481,219	\$ 462,377
Rest-of-World <sup>(1)</sup>	14,555	16,044
Total	\$ 495,774	\$ 478,421

(1) Facilities principally located in the United Kingdom.

F-44

#### UNITED THERAPEUTICS CORPORATION

#### **Notes to Consolidated Financial Statements (Continued)**

#### 18. Quarterly Financial Information (Unaudited)

Summarized quarterly financial information for each of the years ended December 31, 2015 and 2014 are as follows (in thousands, except per share amounts):

	Quarter Ended								
	De	ecember 31, 2015	Se	eptember 30, 2015		June 30, 2015	N	Iarch 31, 2015	
Total revenues	\$	404,875	\$	386,221	\$	347,161	\$	327,504	
Cost of product sales		25,309		6,891		16,058		20,778	
Gross profit		379,566		379,330		331,103		306,726	
Net income (loss) <sup>(1)(2)</sup>		104,644		464,425		99,211		(16,641)	
Net income (loss) per share basic	\$	2.29	\$	10.20	\$	2.15	\$	(0.36)	
Net income (loss) per share diluted	\$	2.10	\$	9.24	\$	1.91	\$	(0.36)	

	Quarter Ended								
	December 31, 2014		September 30, 2014		June 30, 2014		March 31, 2014		
Total revenues	\$	346,363	\$	329,950	\$	322,802	\$	289,403	
Cost of product sales		15,770		40,804		38,709		30,600	
Gross profit		330,593		289,147		284,093		258,803	
Net income (loss) <sup>(3)</sup>		115,935		(25,237)		111,852		137,524	
Net income (loss) per share basic	\$	2.44	\$	(0.53)	\$	2.35	\$	2.73	
Net income (loss) per share diluted	\$	2.17	\$	(0.53)	\$	2.10	\$	2.43	

- Operating results for the quarter ended December 31, 2015, September 30, 2015, June 30, 2015 and March 31, 2015 include \$71.6 million, \$(75.7) million, \$27.5 million and \$145.7 million net of tax expense (benefit) to operating expenses for STAP related share-based compensation expense, respectively.
- Operating results for the quarter ended September 30, 2015, include a gain on sale of the PPRV we received from the FDA in connection with the approval of Unituxin, for \$350.0 million in cash. The proceeds from the sale of the PPRV were recognized as a gain on the sale of an intangible asset, as the PPRV did not have a carrying value on our consolidated balance sheet at the time of sale.
- Operating results for the quarter ended December 31, 2014, September 30, 2014, June 30, 2014, and March 31, 2014 include \$19.9 million, \$122.1 million, \$(1.4) million and \$(39.6) million net of tax expense (benefit) to operating expenses for STAP related share-based compensation expense, respectively.

### 19. Litigation

Sandoz Inc.

In February 2012, we received a Paragraph IV certification notice letter (the Original Notice Letter) from Sandoz Inc. (Sandoz) advising that Sandoz had submitted an abbreviated new drug application (ANDA) to the FDA requesting approval to market a generic version of the 10 mg/mL strength of Remodulin. In December 2012, we received notice (the Second Notice Letter) that Sandoz

Table of Contents

#### UNITED THERAPEUTICS CORPORATION

#### **Notes to Consolidated Financial Statements (Continued)**

#### 19. Litigation (Continued)

had amended its previously filed ANDA to request additional approval to market generic versions of the 1 mg/mL, 2.5 mg/mL, and 5 mg/mL strengths of Remodulin. In the Original Notice Letter and the Second Notice Letter, Sandoz stated that it intends to market a generic version of Remodulin before the expiration of the following patents relating to Remodulin: U.S. Patent No. 5,153,222, which expired in October 2014; U.S. Patent No. 6,765,117, which expires in October 2017; and U.S. Patent No. 7,999,007, which expires in March 2029. Each of these patents is listed in the FDA's Orange Book, which contains a listing of patents covering a drug or biologic or its method of use, and which have been submitted to the FDA by the filer of a New Drug Application. We responded to the Original Notice Letter by filing a lawsuit in March 2012 against Sandoz in the U.S. District Court for the District of New Jersey alleging patent infringement (the First Action). We responded to the Second Notice Letter by filing an additional lawsuit in January 2013 for patent infringement in the U.S. District Court for the District of New Jersey (the Second Action). Sandoz filed counterclaims in each action alleging that the patents at issue in the litigation are invalid or will not be infringed by the commercial manufacture, use or sale of the proposed product described in Sandoz's ANDA submission. Shortly before trial, Sandoz withdrew its request to market a generic version of Remodulin before the expiration of U.S. Patent No. 5,153,222, but maintained its request to market a generic version of Remodulin before the expiration of the other two patents. The trial for both lawsuits, limited to U.S. Patent Nos. 6,765,117 and 7,999,007, occurred in May and June 2014 and we received the Court's decision in August 2014. In that decision, with respect to U.S. Patent No. 6,765,117 the Court both ruled that the patent is valid and enforceable against Sandoz, and enjoined Sandoz from marketing its generic product until the expiration of that patent in October 2017. With respect to U.S. Patent No. 7,999,007, the Court ruled that the patent is valid, but that it would not be infringed by Sandoz's generic product.

Sandoz appealed the ruling that U.S. Patent No. 6,765,117 is valid and would be infringed, and that U.S. Patent No. 7,999,007 is valid. We filed a cross-appeal challenging the Court's ruling that U.S. Patent No. 7,999,007 would not be infringed by Sandoz's generic version of Remodulin.

In July 2014, we received an additional Paragraph IV certification notice letter (Third Notice Letter) from Sandoz, seeking permission to market and sell its generic version of Remodulin before the expiration of U.S. Patent No. 8,497,393, which expires in December 2028 and is also listed in the Orange Book. We responded to Sandoz's Third Notice Letter by filing a lawsuit in September 2014 in the U.S. District Court for the District of New Jersey for patent infringement with respect to U.S. Patent No. 8,497,393 (the Third Action).

On September 29, 2015, we entered into a Settlement Agreement with Sandoz to settle all ongoing litigation between the parties (all three lawsuits described above, including pending appeals) concerning Remodulin patents. Under the settlement agreement, we granted Sandoz a non-exclusive license to manufacture and commercialize in the United States the generic version of Remodulin described in Sandoz's ANDA filing beginning on June 26, 2018, although Sandoz may be permitted to enter the market earlier under certain circumstances. The settlement agreement does not grant Sandoz a license to manufacture a generic version of any other product, such as Tyvaso or Orenitram, nor does it grant any rights with respect to any technology associated with the Remodulin Implantable System we are developing in conjunction with Medtronic Inc., or the pre-filled semi-disposable pump system we are developing with DEKA Research & Development Corp. The settlement agreement does not grant Sandoz any rights other than those required to launch Sandoz's generic version of Remodulin.

Table of Contents

#### UNITED THERAPEUTICS CORPORATION

#### **Notes to Consolidated Financial Statements (Continued)**

#### 19. Litigation (Continued)

In accordance with the terms of the settlement agreement, the parties have submitted the settlement agreement to the U.S. Federal Trade Commission and the U.S. Department of Justice for review. The parties have terminated the appeal relating to the First Action and the Second Action. The parties' claims in the Third Action have been dismissed with prejudice. Following a motion by the parties, the U.S. District Court vacated the portions of the ruling in the First Action and Second Action regarding whether Sandoz's ANDA product infringed U.S. Patent Nos. 6,765,117 and 7,999,007. The vacatur did not affect the portions of the Court's decisions that these patents are valid.

Teva Pharmaceuticals USA, Inc.

On July 21, 2014, we received a Paragraph IV certification notice letter from Teva Pharmaceuticals USA, Inc. (Teva) advising that Teva had submitted an ANDA to the FDA requesting approval to market a generic version of Remodulin. In its notice letter, Teva states that it intends to market a generic version of Remodulin before the expiration of U.S. Patent Nos. 6,765,117 and 8,497,393, both of which are also the subject of Paragraph IV certifications by Sandoz, as discussed above. Teva's notice letter states that the ANDA contains a Paragraph IV certification alleging that these patents are not valid, not enforceable and/or will not be infringed by the commercial manufacture, use or sale of the proposed product described in Teva's ANDA submission.

We responded to Teva's notice letter by filing a lawsuit in September 2014 against Teva in the U.S. District Court for the District of New Jersey alleging infringement of U.S. Patent Nos. 6,765,117, 7,999,007 and 8,497,393, as well as infringement of U.S. Patent Nos. 8,653,137 and 8,658,694, both of which expire in September 2028.

On January 15, 2016, we entered into a Settlement Agreement with Teva to settle the parties' ongoing litigation concerning Remodulin patents. Under the settlement agreement, we granted Teva a non-exclusive license beginning on December 23, 2018 to manufacture and commercialize in the United States the generic version of Remodulin described in Teva's ANDA filing, although Teva may be permitted to enter the market earlier under certain circumstances. The settlement agreement does not grant Teva a license to manufacture a generic version of any other product, such as Tyvaso or Orenitram, nor does it grant any rights with respect to any technology associated with the Remodulin Implantable System we are developing in conjunction with Medtronic Inc., or the pre-filled semi-disposable pump system we are developing with DEKA Research & Development Corp. The settlement agreement does not grant Teva any rights other than those required to launch Teva's generic version of Remodulin. In accordance with the terms of the settlement agreement, the parties have submitted the settlement agreement to the U.S. Federal Trade Commission and the U.S. Department of Justice for review. The parties have also terminated the outstanding lawsuit.

Watson Laboratories, Inc.

In June 2015, we received a Paragraph IV certification notice letter from Watson Laboratories, Inc. (Watson) indicating that Watson has submitted an ANDA to the FDA to market a generic version of Tyvaso. In its notice letter, Watson states that it intends to market a generic version of Tyvaso before the expiration of U.S. Patent Nos. 6,521,212 and 6,756,033, each of which expires in November 2018; and U.S. Patent No. 8,497,393, which expires in December 2028. Watson's notice letter states that the ANDA contains a Paragraph IV certification alleging that these patents are not valid, not enforceable, and/or will not be infringed by the commercial manufacture, use or sale of the proposed product

Table of Contents

#### UNITED THERAPEUTICS CORPORATION

#### **Notes to Consolidated Financial Statements (Continued)**

#### 19. Litigation (Continued)

described in Watson's ANDA submission. We responded to the Watson notice letter by filing a lawsuit on July 22, 2015 against Watson in the U.S. District Court for the District of New Jersey alleging infringement of U.S. Patent Nos. 6,521,212, 6,756,033, and 8,497,393. Under the Hatch-Waxman Act, the FDA is automatically precluded from approving Watson's ANDA for up to 30 months from receipt of Watson's notice letter or until the issuance of a U.S. District Court decision that is adverse to us, whichever occurs first. On September 1, 2015, Watson filed (1) a motion to dismiss some, but not all, counts of the complaint, and (2) its answer to the complaint as well as certain counterclaims against us. The Court granted Watson's motion to dismiss certain counts of our complaint. On September 25, 2015, we filed our answer to Watson's counterclaims. The parties are currently engaged in discovery, and trial is currently scheduled to take place in September 2017.

We intend to vigorously enforce our intellectual property rights relating to Tyvaso.

SteadyMed Ltd.

On October 1, 2015, SteadyMed Ltd. (SteadyMed) filed a petition with the Patent Trial and Appeal Board (PTAB) of the U.S. Patent and Trademark Office for *inter partes* review (the IPR Petition) of U.S. Patent No. 8,497,393 (the '393 Patent), which is owned by United Therapeutics. In its IPR Petition, SteadyMed seeks to invalidate '393 Patent, which expires in December 2028 and covers a method of making treprostinil, which is the active pharmaceutical ingredient in our Remodulin, Tyvaso and Orenitram products. The '393 Patent was also the subject of the recently-settled Sandoz and Teva litigation, and remains the subject of our pending litigation with Watson, described above. We filed a response to the IPR Petition in January 2016 and intend to vigorously defend the '393 Patent. SteadyMed has announced that it is developing a product called Trevyent , which is a single-use, pre-filled pump it plans to seek FDA approval for delivery of a two-day supply of treprostinil subcutaneously using its PatchPump® technology. We expect the PTAB to decide whether to institute the review of the '393 patent requested by SteadyMed by mid-April 2016.

## Table of Contents

## United Therapeutics Corporation Schedule II Valuation and Qualifying Accounts Years Ended December 31, 2015, 2014, and 2013 (In thousands)

## Valuation Allowance on Deferred Tax Assets

	Balance at Beginning of Year		Additions Charged to Expense		Deductions		alance at d of Year
Year Ended December 31, 2015	\$	2,981	\$	411	\$		\$ 3,392
Year Ended December 31, 2014	\$	2,507	\$	474	\$		\$ 2,981
Year Ended December 31, 2013	\$	5,665	\$	169	\$	(3,327)	\$ 2,507

Docorvo	for	Inventory	Obco	locconco
Keserve	IOI:	mvemorv	ODSO	iescence

	Balance at Beginning of Year		Additions Charged to Expense		Deductions		Balance at End of Year	
Year Ended December 31, 2015	\$	10,537	\$	7,913	\$	(6,286)	\$	12,164
Year Ended December 31, 2014	\$	18,301	\$	3,431	\$	(11,195)	\$	10,537
Year Ended December 31, 2013	\$	16,679	\$	3,341	\$	(1,719)	\$	18,301
					F-49			

#### **Table of Contents**

# ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

#### ITEM 9A. CONTROLS AND PROCEDURES

#### Evaluation of Disclosure Controls and Procedures

Our management, with participation of our Chairman and Co-Chief Executive Officer, President and Co-Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as of December 31, 2015. Based on that evaluation, our Chairman and Co-Chief Executive Officer, President and Co-Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2015.

### Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended). Our internal control over financial reporting was designed to provide reasonable assurance to our management and Board of Directors regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. All internal controls over financial reporting may not prevent or detect misstatements. Therefore, even those internal controls determined to be effective can provide only reasonable assurance with respect to the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2015, based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control Integrated Framework* (2013). Management's assessment included an evaluation of the design of our internal control over financial reporting and testing of the operational effectiveness of our internal control over financial reporting. Based on this assessment, our management concluded that, as of December 31, 2015, our internal control over financial reporting was effective.

Ernst & Young LLP, an independent registered public accounting firm, has issued an attestation report on our internal control over financial reporting. The report of Ernst & Young LLP is contained in *Item 8* of this Annual Report on Form 10-K.

#### Attestation of Independent Registered Public Accounting Firm

The attestation report of our independent registered public accounting firm regarding internal control over financial reporting is set forth in *Item 8* of this Annual Report on Form 10-K under the caption "Report of Independent Registered Public Accounting Firm" and incorporated herein by reference.

#### Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2015 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

#### Table of Contents

#### ITEM 9B. OTHER INFORMATION

#### Paragraph IV Notice Letter for Orenitram

On February 18, 2016, we received a Paragraph IV Certification Notice Letter (the Notice Letter) from Actavis Laboratories FL, Inc. (Actavis) advising that Actavis has submitted an Abbreviated New Drug Application (ANDA) to the U.S. Food and Drug Administration (FDA) requesting approval to market a generic version of the 2.5 mg strength of Orenitram® (treprostinil) Extended-Release Tablets.

In the Notice Letter, Actavis states that it intends to market a generic version of Orenitram before the expiration of U.S. Patent No. 7,417,070, which expires in July 2026; U.S. Patent No. 7,544,713, which expires in July 2024; U.S. Patent No. 8,252,839, which expires in May 2024; U.S. Patent No. 8,349,892, which expires in January 2031; U.S. Patent No. 8,410,169, which expires in February 2030; U.S. Patent No. 8,497,393, which expires in December 2028; U.S. Patent No. 9,050,311, which expires in May 2024; and U.S. Patent No. 8,747,897, which expires in October 2029. The Notice Letter states that the ANDA contains a Paragraph IV Certification alleging that these patents are not valid, not enforceable, and/or will not be infringed by the commercial manufacture, use or sale of the proposed product described in Actavis ANDA submission.

We intend to vigorously enforce our intellectual property rights relating to Orenitram, including the patents mentioned above, which are listed in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations list (the Orange Book).

We are currently reviewing the Notice Letter, which was directed to eight of the nine Orange Book-listed patents for Orenitram. The only patent not included expires in October 2017. We have 45 days from receipt of the Notice Letter to commence a patent infringement lawsuit against Actavis to trigger a stay precluding FDA from approving Actavis's ANDA for up to 30 months or entry of judgment holding the patents invalid, unenforceable, or not infringed, whichever occurs first.

#### **Table of Contents**

#### **PART III**

#### ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information as to the individuals serving on our board of directors is set forth below under the heading *Board of Directors*. Additional information required by Item 10 regarding nominees and directors appearing under Proposal No. 1: *Election of Directors* in our definitive proxy statement for our 2016 annual meeting of shareholders scheduled for June 28, 2016 (the 2016 Proxy Statement) is hereby incorporated herein by this reference. Information regarding our executive officers appears in *Item 1* of this Annual Report on Form 10-K under the heading *Executive Officers of the Registrant*. Information regarding the Audit Committee and the Audit Committee's financial expert appearing under the heading *Committees of our Board of Directors Audit Committee* in our 2016 Proxy Statement is hereby incorporated herein by this reference.

Information appearing under the heading *Section 16(a) Beneficial Ownership Reporting Compliance* in our 2016 Proxy Statement is hereby incorporated herein by this reference.

We have a written Code of Conduct and Business Ethics that applies to our co-principal executive officers, principal financial officer and our principal accounting officer and every other director, officer and employee of United Therapeutics. The Code of Conduct and Business Ethics is available on our Internet website at <a href="http://ir.unither.com/corporate-governance.cfm">http://ir.unither.com/corporate-governance.cfm</a>. A copy of the Code of Conduct and Business Ethics will be provided free of charge by making a written request and mailing it to our corporate headquarters offices to the attention of the Investor Relations Department. If any amendment to, or a waiver from, a provision of the Code of Conduct and Business Ethics that applies to the principal executive officer, principal financial officer and principal accounting officer is made, such information will be posted on our Internet website within four business days at <a href="https://www.unither.com">www.unither.com</a>.

#### **Board of Directors**

Christopher Causey, M.B.A.

Principal, Causey Consortium

Raymond Dwek, F.R.S.

Director of the Glycobiology Institute and Professor Emeritus, University of Oxford

**Richard Giltner** 

Private Investor

Roger Jeffs, Ph.D.

President and Co-Chief Executive Officer of United Therapeutics

Katherine Klein, Ph.D.

Vice-Dean and Professor, The Wharton School of the University of Pennsylvania

Ray Kurzweil

Director of Engineering, Google Inc.

Judy D. Olian, Ph.D.

Dean, UCLA Anderson School of Management and John E. Anderson Chair in Management

Christopher Patusky, J.D., M.G.A.

Founding Principal, Patusky Associates, LLC

Martine Rothblatt, Ph.D., J.D., M.B.A.

Chairman and Co-Chief Executive Officer of United Therapeutics

Louis Sullivan, M.D.

Former Secretary, U.S. Department of Health and Human Services

Tommy Thompson, J.D.

Former Secretary, U.S. Department of Health and Human Services

86

#### **Table of Contents**

#### ITEM 11. EXECUTIVE COMPENSATION

Information concerning executive compensation required by Item 11 will appear under the headings Director Compensation,

Compensation Discussion and Analysis, Summary Compensation Table and Grants of Plan-Based Awards in 2015, Narratives to Summary

Compensation Table and Grants of Plan-Based Awards Table, Summary of Terms of Plan-Based Awards, Supplemental Executive Retirement

Plan, Rabbi Trust, Potential Payments Upon Termination or Change in Control, and Director Compensation in our 2016 Proxy Statement and is incorporated herein by reference.

Information concerning the Compensation Committee required by Item 11 will appear under the heading *Compensation Committee Report* in our 2016 Proxy Statement and is incorporated herein by reference.

# ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information regarding beneficial ownership of our common stock required by Item 12 will appear under *Beneficial Ownership of Common Stock* in our 2016 Proxy Statement and is incorporated herein by reference.

#### Securities Authorized for Issuance Under Equity Compensation Plans

The following table presents information as of December 31, 2015, regarding our securities authorized for issuance under equity compensation plans:

Plan category	Number of securities to be issued upon exercise of outstanding options (a)	Weighted average exercise price of outstanding options	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plan approved by	3.247.438	\$ 93.09	15.233.766
security holders Equity compensation plans not approved by	3,247,438	\$ 95.09	13,233,700
security holders		0.00	N/A
Total	3,247,438	\$ 93.09	15,233,766

All outstanding stock options were issued under our two equity incentive plans approved by security holders in 1999 (the 1999 Plan) and 2015 (the 2015 Plan). Information regarding these plans is contained in Note 11 *Stockholders' Equity* to the consolidated financial statements included in this Annual Report on Form 10-K. Aside from stock options issued under the 1999 Plan and the 2015 Plan, we do not have any outstanding stock options, warrants or rights that are outstanding or available for issuance as described in Regulation S-K Item 201(d). No further awards will be issued under the 1999 Plan.

#### ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Information concerning related party transactions and director independence required by Item 13 will appear under the headings *Other Matters Certain Relationships and Related Party Transactions, Board of Directors, Committees, Corporate Governance Director Independence and Committees of our Board of Directors* in our 2016 Proxy Statement and is incorporated herein by reference.

### Table of Contents

#### ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Information required by Item 14 concerning the principal accounting fees paid by the Registrant and the Audit Committee's pre-approval policies and procedures, will appear under the heading *Report of the Audit Committee and Information on our Independent Auditors* in our 2016 Proxy Statement and is incorporated herein by reference.

88

Table of Contents

#### PART IV

#### ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

In reviewing the agreements included or incorporated by reference as exhibits to this Annual Report on Form 10-K, it is important to note that they are included to provide investors with information regarding their terms, and are not intended to provide any other factual or disclosure information about United Therapeutics or the other parties to the agreements. The agreements contain representations and warranties made by each of the parties to the applicable agreement. These representations and warranties have been made solely for the benefit of the other parties to the applicable agreement, and: (1) should not be treated as categorical statements of fact, but rather as a way of allocating risk between the parties; (2) have in some cases been qualified by disclosures that were made to the other party in connection with the negotiation of the applicable agreement, which disclosures are not necessarily reflected in the agreement; (3) may apply standards of materiality in a way that is different from what may be material to investors; and (4) were made only as of the date of the applicable agreement or such other date or dates as may be specified in the agreement and are subject to more recent developments.

Accordingly, these representations and warranties may not describe the actual state of affairs as of the date they were made or at any other time. Additional information about United Therapeutics may be found elsewhere in this Annual Report on Form 10-K and our other public filings, which are available without charge through the SEC's website at <a href="http://www.sec.gov">http://www.sec.gov</a>.

- (a)(1) Our financial statements filed as part of this report on Form 10-K are set forth in the Index to Consolidated Financial Statements under Part II, Item 8 of this Form 10-K.
- (a)(2) The Schedule II Valuation and Qualifying Accounts is filed as part of this Form 10-K. All other schedules are omitted because they are not applicable or not required, or because the required information is included in the consolidated statements or notes thereto.
- (a)(3) Exhibits filed as a part of this Form 10-K are listed on the Exhibit Index, which is incorporated by reference herein.

  Certain exhibits to this report have been included only with the copies of this report filed with the Securities and Exchange

  Commission. Copies of individual exhibits will be furnished to shareholders upon written request to United Therapeutics and payment of a reasonable fee (covering the expense of furnishing copies). Shareholders may request exhibit copies by contacting: United Therapeutics Corporation, Attn: Investor Relations, 1040 Spring Street, Silver Spring, Maryland 20910.

#### Table of Contents

#### **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, thereto duly authorized.

	UNITED T	ED THERAPEUTICS CORPORATION	
	By:	/s/ MARTINE A. ROTHBLATT	
February 25, 2016		Martine A. Rothblatt, Ph.D.  Chairman and Co-Chief Executive Officer	
	By:	/s/ ROGER A. JEFFS	_
		Roger A. Jeffs, Ph.D.	

February 25, 2016 President and Co-Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Title Signatures Date /s/ MARTINE A. ROTHBLATT Chairman and Co-Chief Executive Officer February 25, 2016 (Co-Principal Executive Officer) Martine A. Rothblatt /s/ ROGER A. JEFFS President, Co-Chief Executive Officer and Director February 25, 2016 (Co-Principal Executive Officer) Roger A. Jeffs /s/ JAMES C. EDGEMOND Chief Financial Officer and Treasurer (Principal February 25, 2016 Financial Officer and Principal Accounting Officer) James C. Edgemond /s/ CHRISTOPHER CAUSEY Director February 25, 2016 Christopher Causey /s/ RAYMOND DWEK Director February 25, 2016 Raymond Dwek /s/ RICHARD GILTNER Director February 25, 2016 Richard Giltner 90

Signatures	Title	Date
/s/ KATHERINE KLEIN	D'	E 1 25 2017
Katherine Klein	Director	February 25, 2016
/s/ RAYMOND KURZWEIL	Director	Fohrmony 25, 2016
Raymond Kurzweil	Director	February 25, 2016
/s/ JUDY D. OLIAN	Director	Fohrmory 25, 2016
Judy D. Olian	Director	February 25, 2016
/s/ CHRISTOPHER PATUSKY	Director	February 25, 2016
Christopher Patusky	Director	rebluary 23, 2010
/s/ LOUIS W. SULLIVAN	D.	E.L. 25 2016
Louis W. Sullivan	Director	February 25, 2016
/s/ TOMMY THOMPSON	D.	E.L. 25 2016
Tommy Thompson	Director 91	February 25, 2016

## Table of Contents

### EXHIBIT INDEX

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.1 of the Registrant's Registration Statement on Form S-1 (Registration No. 333-76409).
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K, filed on June 28, 2010.
3.3	Fourth Amended and Restated By-laws of the Registrant, incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed on June 26, 2015.
3.4	Form of Certificate of Designation, Preferences and Rights of Series A Junior Participating Preferred Stock of the Registrant, incorporated by reference to Exhibit A to Exhibit 4 to the Registrant's Current Report on Form 8-K, filed December 18, 2000.
4.1	Reference is made to Exhibits 3.1, 3.2, 3.3 and 3.4.
4.2	First Amended and Restated Rights Agreement, incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K filed on July 3, 2008.
4.3	Indenture, dated as of October 17, 2011, between the Registrant and The Bank of New York Mellon Trust Company, N.A., as trustee (including form of 1.0% Convertible Senior Note due September 15, 2016), incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K filed October 17, 2011.
4.4	Form of 1.0% Convertible Senior Note due September 15, 2016, incorporated by reference to Exhibit 4.2 of the Registrant's Current Report on Form 8-K filed October 17, 2011.
10.1**	United Therapeutics Corporation Amended and Restated Equity Incentive Plan, as amended effective as of September 24, 2004, incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2004.
10.2**	Amended and Restated Executive Employment Agreement dated as of January 1, 2009, between the Registrant and Martine A. Rothblatt, incorporated by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2009.
10.3**	Employment Agreement dated as of June 16, 2001 between the Registrant and Paul A. Mahon, incorporated by reference to Exhibit 10.4 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2002.
10.4**	Employment Agreement dated November 29, 2000 between the Registrant and Roger Jeffs, incorporated by reference to Exhibit 10.9 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2002.
10.5	Form of Indemnification Agreement between the Registrant and each of its Directors and Executive Officers, incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2009.
10.6**	Amendment dated December 11, 2002 to Employment Agreement between the Registrant and Roger Jeffs, incorporated by reference to Exhibit 10.40 of the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2002.

Exhibit No. 10.7**	Description  Amendment dated December 11, 2002 to Employment Agreement between the Registrant and Paul Mahon, incorporated by
	reference to Exhibit 10.43 of the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2002.
10.8**	Amendment dated December 29, 2004 to Employment Agreement between Roger Jeffs and the Registrant dated November 29, 2000, as previously amended, incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed on December 29, 2004.
10.9**	Amendment dated December 29, 2004 to Employment Agreement between Paul A. Mahon and the Registrant dated June 16, 2001, as previously amended, incorporated by reference to Exhibit 10.4 of the Registrant's Current Report on Form 8-K filed on December 29, 2004.
10.10**	Form of terms and conditions for awards granted to Employees by the Registrant under the Amended and Restated Equity Incentive Plan, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on December 17, 2004.
10.11**	Form of Terms and Conditions for Awards granted to Non-Employees by the Registrant under the Amended and Restated Equity Incentive Plan, incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed on December 17, 2004.
10.12**	United Therapeutics Corporation Supplemental Executive Retirement Plan, effective as of July 1, 2006, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on May 4, 2006.
10.13**	Employment Agreement, dated as of August 2, 2006, between John Ferrari and the Registrant, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on August 4, 2006.
10.14**	Amendment, dated as of July 31, 2006, to amended Employment Agreement, dated November 29, 2000, between Roger Jeffs and the Registrant, incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed on August 4, 2006.
10.15**	Amendment, dated as of July 31, 2006, to amended Employment Agreement, dated June 16, 2001, between Paul A. Mahon and the Registrant, incorporated by reference to Exhibit 10.3 of the Registrant's Current Report on Form 8-K filed on August 4, 2006.
10.16**	Amendment, dated as of December 28, 2006, to Employment Agreement, dated August 2, 2006, between John Ferrari and the Registrant, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on December 29, 2006.
10.17	United Therapeutics Corporation Supplemental Executive Retirement Plan Rabbi Trust Document entered into on December 28, 2007, by and between the Registrant and Wilmington Trust Company, as trustee, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on December 28, 2007.
10.18**	United Therapeutics Corporation Share Tracking Awards Plan, incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008.
10.19**	First Amendment to the United Therapeutics Corporation Share Tracking Awards Plan, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on September 18, 2009.
	22

Exhibit No. 10.20**	Description Second Amendment to the United Therapeutics Corporation Share Tracking Awards Plan, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on February 6, 2012.
10.21**	Form of terms and conditions for awards granted to non-employees by the Registrant under the United Therapeutics Corporation Share Tracking Awards Plan, incorporated by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008.
10.22**	Form of terms and conditions for awards granted to employees by the Registrant prior to January 1, 2010, under the United Therapeutics Corporation Share Tracking Awards Plan, incorporated by reference to Exhibit 10.3 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008.
10.23**	Form of terms and conditions for awards granted to employees by the Registrant on or after January 1, 2010, under the United Therapeutics Corporation Share Tracking Awards Plan, incorporated by reference to Exhibit 10.48 of the Registrant's Annual Report on Form 10-K for the year ended December 31, 2009.
10.24**	Form of terms and conditions for awards granted to employees on or after March 15, 2011 under the United Therapeutics Corporation 2011 Share Tracking Awards Plan and the United Therapeutics Corporation 2008 Share Tracking Awards Plan, incorporated by reference to Exhibit 10.2 of Registrant's Registration Statement on Form S-8 (Registration No. 333-173858) filed on May 2, 2011.
10.25**	Form of grant letter used by Registrant under the United Therapeutics Corporation Share Tracking Awards Plan, incorporated by reference to Exhibit 10.4 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008.
10.26**	United Therapeutics Corporation 2011 Share Tracking Awards Plan, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on March 18, 2011.
10.27**	First Amendment to the United Therapeutics Corporation 2011 Share Tracking Awards Plan, incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed on February 6, 2012.
10.28**	Second Amendment to the United Therapeutics Corporation 2011 Share Tracking Awards Plan, incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2012.
10.29**	Third Amendment to the United Therapeutics Corporation 2011 Share Tracking Awards Plan, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on February 4, 2013.
10.30**	Fourth Amendment to the United Therapeutics Corporation 2011 Share Tracking Awards Plan, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on January 31, 2014.
10.31**	Form of terms and conditions for awards granted to employees by the Registrant on or after March 15, 2011 under the United Therapeutics Corporation Share Tracking Awards Plan or the United Therapeutics Corporation 2011 Share Tracking Awards Plan, incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed on March 18, 2011.

Exhibit No. 10.32**	Description  Form of terms and conditions for awards granted to non-employees by the Registrant on or after March 15, 2011 under the United Therapeutics Corporation Share Tracking Awards Plan or the United Therapeutics Corporation 2011 Share Tracking Awards Plan, incorporated by reference to Exhibit 10.3 of the Registrant's Current Report on Form 8-K filed on March 18, 2011.
10.33**	Form of grant letter used by Registrant under the United Therapeutics Corporation 2011 Share Tracking Awards Plan, incorporated by reference to Exhibit 10.4 of the Registrant's Current Report on Form 8-K filed on March 18, 2011.
10.34**	United Therapeutics Corporation Employee Stock Purchase Plan, incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2012.
10.35*	License Agreement, dated as of November 14, 2008, by and between Eli Lilly and Company and the Registrant, incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed on December 24, 2008.
10.36*	Manufacturing and Supply Agreement, dated as of November 14, 2008, by and between Eli Lilly and Company, Lilly del Caribe, Inc. and the Registrant incorporated by reference to Exhibit 10.3 of the Registrant's Current Report on Form 8-K filed on December 24, 2008.
10.37**	Form of Amendment to Employment Agreement between the Registrant and each of Roger Jeffs, Paul Mahon and John Ferrari, each dated as of January 1, 2009, incorporated by reference to Exhibit 10.3 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2009.
10.38**	Form of Amendment to Employment Agreements between the Registrant and each of Roger Jeffs, Paul Mahon and John Ferrari, each dated as of February 22, 2010, incorporated by reference to Exhibit 10.46 of the Registrant's Annual Report on Form 10-K for the year ended December 31, 2009.
10.39	Distribution Agreement relating to Tyvaso, dated as of August 17, 2009 between the Registrant and Accredo Health Group, Inc., incorporated by reference to Exhibit 10.47 of the Registrant's Annual Report on Form 10-K for the year ended December 31, 2009.
10.40	First Amendment to Distribution Agreement relating to Tyvaso, dated as of September 1, 2011, between the Registrant and Accredo Health Group, Inc., incorporated by reference to Exhibit 10.44 of the Registrant's Annual Report on Form 10-K for the year ended December 31, 2013.
10.41	Second Amendment to Distribution Agreement relating to Tyvaso, dated as of December 18, 2013, between the Registrant, Accredo Health Group, Inc., CuraScript, Inc. and Priority Healthcare Distribution, Inc., incorporated by reference to Exhibit 10.45 of the Registrant's Annual Report on Form 10-K for the year ended December 31, 2013.
10.42	Stipulation of Settlement, dated October 25, 2010, among the parties to a derivative lawsuit against the directors and officers of the Registrant identified therein, incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2010.

Exhibit No. 10.43***	Description  Amended and Restated Distribution Agreement relating to Remodulin, dated as of February 21, 2011, between the Registrant and Accredo Health Group, Inc., incorporated by reference to Exhibit 10.38 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2010.
10.44	First Amendment to Amended and Restated Distribution Agreement relating to Remodulin, dated as of December 18, 2013, between the Registrant, Accredo Health Group, Inc., CuraScript, Inc. and Priority Healthcare Distribution, Inc., incorporated by reference to Exhibit 10.49 of the Registrant's Annual Report on Form 10-K for the year ended December 31, 2013.
10.45*	Confirmation, dated October 11, 2011, of a note hedging transaction between the Registrant and Deutsche Bank AG, London Branch, incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2011.
10.46*	Confirmation, dated October 11, 2011, of a warrant transaction between the Registrant and Deutsche Bank AG, London Branch, incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2011.
10.47	Credit Agreement dated as of September 26, 2013, by and among the Registrant, the lenders party thereto from time to time, Wells Fargo Bank, National Association, as the Administrative Agent, and a subsidiary of the Registrant, as guarantor, incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed September 27, 2013.
10.48**	Amendment to Amended and Restated Executive Employment Agreement between the Registrant and Martine Rothblatt, Ph.D., dated as of January 1, 2015, incorporated by reference to Exhibit 10.1 to Registrant's Current Report on Form 8-K filed December 17, 2014.
10.49**	Employment Agreement, dated as of June 26, 2006, between the Company and David Zaccardelli, Pharm.D., together with three amendments thereto, dated January 26, 2007, September 23, 2009 and February 24, 2010, respectively, incorporated by reference to Exhibit 10.2 to Registrant's Current Report on Form 8-K filed December 17, 2014.
10.50**	Change in Control Severance Agreement between the Company and David Zaccardelli, Pharm.D., dated as of February 14, 2012, incorporated by reference to Exhibit 10.3 to Registrant's Current Report on Form 8-K filed December 17, 2014.
10.51	Amendment No. 1 to Credit Agreement, dated as of July 24, 2014, by and among the Registrant, the lenders party thereto from time to time, Wells Fargo Bank, National Association, as the Administrative Agent, and a subsidiary of the Registrant, as guarantor, incorporated by reference to Exhibit 10.1 to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2014.
10.52**	United Therapeutics Corporation Section 162(m) Bonus Plan, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed June 27, 2014.
10.53*	Third Amendment to Distribution Agreement relating to Tyvaso, dated October 20, 2014, by and among the Registrant, Accredo Health Group, Inc., CuraScript, Inc., and Priority Healthcare Distribution, Inc, incorporated by reference to Exhibit 10.54 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2014.
	96

<b>Exhibit No.</b> 10.54**	Description  Employment Agreement, dated as of March 13, 2015, between the Company and James Edgemond, incorporated by reference to Exhibit 10.55 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2014.
10.55**	Change in Control Severance Agreement between the Company and James Edgemond, dated as of November 12, 2014, incorporated by reference to Exhibit 10.56 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2014.
10.56**	United Therapeutics Corporation 2015 Stock Incentive Plan, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on June 29, 2015.
10.57**	Form of Grant Notice and Standard Terms and Conditions for Non-Qualified Stock Options Granted to Non-Employee Directors under the United Therapeutics Corporation 2015 Stock Incentive Plan, incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed on June 29, 2015.
10.58**	Form of Grant Notice and Standard Terms and Conditions for Non-Qualified Stock Options Granted to Certain Executives under the United Therapeutics Corporation 2015 Stock Incentive Plan, incorporated by reference to Exhibit 10.3 of the Registrant's Current Report on Form 8-K filed on June 29, 2015.
10.59**	Form of Grant Notice and Standard Terms and Conditions for Non-Qualified Stock Options Granted to Employees under the United Therapeutics Corporation 2015 Stock Incentive Plan, incorporated by reference to Exhibit 10.4 of the Registrant's Current Report on Form 8-K filed on June 29, 2015.
10.60	Amendment No. 2 to Credit Agreement, dated as of July 24, 2015, by and among the Registrant, the lenders party thereto from time to time, Wells Fargo Bank, National Association, as the Administrative Agent, and a subsidiary of the Registrant, as guarantor, incorporated by reference to Exhibit 10.6 to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015.
10.61**	First Amendment to the United Therapeutics Corporation Amended and Restated Equity Incentive Plan, effective as of June 2, 2015, incorporated by reference to Exhibit 10.1 to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015.
10.62	Asset Purchase Agreement, dated as of August 18, 2015, by and between the Registrant and AbbVie Ireland Unlimited Company, incorporated by reference to Exhibit 2.1 of the Registrant's Current Report on Form 8-K filed on August 19, 2015.
10.63*	Settlement Agreement, dated September 29, 2015, between the Registrant and Sandoz Inc., incorporated by reference to Exhibit 10.2 to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2015.
10.64	Amendment No. 3 to Credit Agreement, dated as of October 12, 2015, by and among the Registrant, the lenders party thereto from time to time, Wells Fargo Bank, National Association, as the Administrative Agent, and a subsidiary of the Registrant, as guarantor, incorporated by reference to Exhibit 10.3 to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2015.
10.65	Credit Agreement, dated as of January 29, 2016, among the Registrant, certain of its subsidiaries party thereto, as guarantors, the lenders referred to therein, and Wells Fargo Bank, National Association, as administrative agent and as a swingline lender, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on February 1, 2016.

#### Table of Contents

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Exhibit No. 21	Description Subsidiaries of the Registrant.
23.1	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm.
31.1	Certification of Co-Principal Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934.
31.2	Certification of Co-Principal Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934.
31.3	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934.
32.1	Certification of Co-Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Co-Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.3	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following financial information from our Annual Report on Form 10-K for the year ended December 31, 2015, filed with the SEC on February 25, 2016, formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets as of December 31, 2015 and 2014, (ii) Consolidated Statements of Operations for each of three years in the period ended December 31, 2015, (iii) Consolidated Statements of Comprehensive Income for each of the three years in the period ended December 31, 2015, (iv) Consolidated Statements of Stockholders' Equity for each of the three years in the period ended December 31, 2015, (v) Consolidated Statements of Cash Flows for each of the three years in the period ended December 31, 2015, and (vi) Notes to Consolidated Financial Statements.

Confidential treatment has been granted with respect to certain portions of this exhibit pursuant to Rule 406 of the Securities Act of 1933, as amended or Rule 24b-2 of the Securities Act of 1934, as amended. The omitted portions of this document have been filed with the Securities and Exchange Commission.

Designates management contracts and compensation plans.

The Company as has requested an extension of confidential treatment for certain portions of this exhibit pursuant to Rule 24b-2 of the Securities Act of 1934, as amended. The omitted portions of this document have been filed with the Securities and Exchange Commission.

Note: Except as otherwise noted above, all exhibits incorporated by reference to the Registrant's previously filed reports with the Securities and Exchange Commission are filed under File No. 000-26301.