RUSSO PATRICIA F
Form 4
November 17, 2005

FORM 4

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

OMB APPROVAL

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STATEMENT OF CHANGES IN BENEFICIAL OWNERSHIP OF SECURITIES

Filed pursuant to Section 16(a) of the Securities Exchange Act of 1934, Section 17(a) of the Public Utility Holding Company Act of 1935 or Section 30(h) of the Investment Company Act of 1940

(Print or Type Responses)

1. Name and Address of Reporting Person *
RUSSO PATRICIA F

(Last) (First) (Middle)

600 MOUNTAIN AVENUE

(Street)

MURRAY HILL, NJ 07974

(City) (State) (Zip)

2. Issuer Name **and** Ticker or Trading Symbol
LUCENT TECHNOLOGIES INC [LU]

3. Date of Earliest Transaction (Month/Day/Year)
11/15/2005

4. If Amendment, Date Original Filed(Month/Day/Year)

5. Relationship of Reporting Person(s) to Issuer
(Check all applicable)
__X__ Director _____ 10% Owner
__X__ Officer (give title below) _____ Other (specify below)
Chairman and CE0

6. Individual or Joint/Group Filing(Check Applicable Line)
_X_ Form filed by One Reporting Person
___ Form filed by More than One Reporting Person

Table I - Non-Derivative Securities Acquired, Disposed of, or Beneficially Owned

1.Title of Security (Instr. 3)	2. Transaction Date (Month/Day/Year)	2A. Deemed Execution Date, if any (Month/Day/Year)	3. Transaction Code (Instr. 8)		4. Securities Acquired (A) or Disposed of (D) (Instr. 3, 4 and 5)			5. Amount of Securities Beneficially Owned Following Reported Transaction(s) (Instr. 3 and 4)	6. Ownership Form: Direct (D) or Indirect (I) (Instr. 4)	7. Nature of Indirect Beneficial Ownership (Instr. 4)
			Code	V	Amount	(A) or (D)	Price			
Common Stock (1)	11/15/2005		A		658,135	A	$ 0	4,041,019	D	
Common Stock								354.283	I	By 401K
Common Stock								350,000	I	By Husband

Reminder: Report on a separate line for each class of securities beneficially owned directly or indirectly.

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SEC 1474 (9-02)

number.

Table II - Derivative Securities Acquired, Disposed of, or Beneficially Owned
(*e.g.*, puts, calls, warrants, options, convertible securities)

1. Title of Derivative Security (Instr. 3)	2. Conversion or Exercise Price of Derivative Security	3. Transaction Date (Month/Day/Year)	3A. Deemed Execution Date, if any (Month/Day/Year)	4. Transaction Code (Instr. 8)		5. Number of Derivative Securities Acquired (A) or Disposed of (D) (Instr. 3, 4, and 5)		6. Date Exercisable and Expiration Date (Month/Day/Year)		7. Title and Amount of Underlying Securities (Instr. 3 and 4)		8. Price of Derivative Security (Instr. 5)	9. Nu Deriv Secur Bene Owne Follo Repo Trans (Instr
				Code	V	(A)	(D)	Date Exercisable	Expiration Date	Title	Amount or Number of Shares		

Reporting Owners

Reporting Owner Name / Address	Relationships			
	Director	10% Owner	Officer	Other
RUSSO PATRICIA F 600 MOUNTAIN AVENUE MURRAY HILL, NJ 07974	X		Chairman and CE0	

Signatures

Patricia F. Russo, by Michael C. Keefe, as attorney-in-fact	11/17/2005
**Signature of Reporting Person	Date

Explanation of Responses:

***** If the form is filed by more than one reporting person, *see* Instruction 4(b)(v).

****** Intentional misstatements or omissions of facts constitute Federal Criminal Violations. *See* 18 U.S.C. 1001 and 15 U.S.C. 78ff(a).

(1) This award represents Restricted Stock Units granted in conjunction with the 2005-2007 performance cycle of the three year performance award program. This award vests in its entirety on November 15, 2006.

Note: File three copies of this Form, one of which must be manually signed. If space is insufficient, *see* Instruction 6 for procedure.
Potential persons who are to respond to the collection of information contained in this form are not required to respond unless the form displays a currently valid OMB number. e="font-family:inherit;font-size:10pt;">Net carrying value of the debt

$
169,440

$
164,167

_____

(1) Included in the consolidated balance sheets within convertible notes and amortized to interest expense over the remaining life of the convertible notes using the effective interest rate method.

The following table sets forth total interest expense recognized related to the Convertible Notes for the three and six months ended June 30, 2018, respectively:

Components (In thousands)	Three months ended June 30, 2018	Six months ended June 30, 2018
Contractual interest expense	$ 1,888	$ 3,775
Amortization of debt discount	2,539	5,011
Amortization of deferred financing	133	262
Total	$ 4,560	$ 9,048

Note 6. Stockholders' Equity

Common Stock and Warrants

On February 15, 2018, the Company announced the pricing of an underwritten offering of 19,354,839 shares of its common stock at $15.50 per share, resulting in gross proceeds of $300.0 million. Under the terms of the underwriting agreement, the Company granted the underwriters an option, exercisable for 30 days after February 16, 2018, to purchase up to an additional 2,903,225 shares of the Company's common stock, which was exercised with respect to 885,000 shares of the Company's common stock at a purchase price of $15.50 per share. The Company received net proceeds of $294.6 million from these offerings, after deducting underwriting discounts and commissions and offering expenses payable by the Company.

In April 2018, 453,214 warrants were exercised at $7.98 per share of common stock resulting in gross cash proceeds of $3.6 million.

On June 7, 2018, the Company's stockholders approved an amendment to the Company's Restated Certificate of Incorporation to increase the number of shares of common stock, par value $0.01 per share, that the Company is authorized to issue from 250,000,000 shares to 500,000,000 shares.

Note 7. Share based Compensation

The Company's Equity Incentive Plans consist of the Amended and Restated 2007 Equity Incentive Plan (the "Plan") and the 2007 Director Option Plan (the "2007 Director Plan"). The Plan provides for the granting of restricted stock units and options to purchase common stock in the Company to employees, advisors and consultants at a price to be determined by the Company's Board of Directors. The Plan is intended to encourage ownership of stock by employees and consultants of the Company and to provide additional incentives for them to promote the success of the Company's business. The 2007 Director Plan is intended to promote the recruiting and retention of highly qualified eligible directors and strengthen the commonality of interest between directors and stockholders by encouraging ownership of common stock of the Company. The Board of Directors, or its committee, is responsible for determining the individuals to be granted options, the number of options each individual will receive, the option price per share, and the exercise period of each option.

Stock Option Grants

The fair value of the stock options granted is estimated on the date of grant using a Black-Scholes option pricing model with the following weighted-average assumptions:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Expected stock price volatility	81%	82%	81%	83%
Risk free interest rate	2.8%	1.9%	2.4%	2.0%
Expected life of options (years)	5.62	6.25	5.62	6.25
Expected annual dividend per share	$—	$ —	$—	$ —

Beginning in the third quarter of 2017, the average expected life was determined using our actual historical data versus a “simplified” method used in prior quarters. The “simplified” method of estimating the expected exercise term uses the mid-point between the vesting date and the end of the contractual term. In earlier quarters, we did not have sufficient reliable exercise data to justify a change from the use of the “simplified” method of estimating the expected exercise term of employee stock option grants. The impact from this change was not material.

A summary of the Company’s stock options for the six months ended June 30, 2018 were as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
	(in thousands)			(in millions)
Options outstanding, December 31, 2017	15,181	$ 7.48		
Granted	1,910	$ 15.49		
Exercised	(1,102)	$ 6.87		
Forfeited	(113)	$ 9.75		
Expired	(7)	10.45		
Options outstanding, June 30, 2018	15,869	$ 8.47	7.2 years	$ 114.0
Vested and unvested expected to vest, June 30, 2018	15,160	$ 8.32	7.1 years	$ 109.6
Exercisable at June 30, 2018	8,916	$ 7.08	6.1 years	$ 76.4

As of June 30, 2018, the total unrecognized compensation cost related to non-vested stock options granted was $39.1 million and is expected to be recognized over a weighted average period of three years.

Restricted Stock Units (“RSUs”) and Performance-Based Restricted Stock Units

RSUs awarded under the Plan are generally subject to graded vesting and are contingent on an employee’s continued service. RSUs are generally subject to forfeiture if employment terminates prior to the release of vesting restrictions. The Company expenses the cost of the RSUs, which is determined to be the fair market value of the shares of common stock underlying the RSUs at the date of grant, ratably over the period during which the vesting restrictions lapse. A summary of non-vested RSU activity under the Plan for the six months ended June 30, 2018 is as follows:

	Number of Shares	Weighted Average Grant Date Fair Value	Weighted Average Remaining Years	Aggregate Intrinsic Value
	(in thousands)			(in millions)
Non-vested units as of December 31, 2017	2,575	$ 5.85		
Granted	1,522	$ 16.77		
Vested	(511)	$ 5.82		
Forfeited	(30)	$ 7.96		
Non-vested units as of June 30, 2018	3,556	$ 10.39	2.9 years	$ 55.5

On December 30, 2016, the Compensation Committee approved a form of Performance-Based Restricted Stock Unit Award Agreement (the “Performance-Based RSU Agreement”), to be used for performance-based RSUs granted to participants under the Amended and Restated Amicus Therapeutics, Inc. 2007 Equity Incentive Plan, including named executive officers. Certain awards under the Performance-Based RSU Agreement were granted in January 2017 and

2018. The 2018 grants include 187,222 market performance-based restricted stock units ("MPRSUs") granted to executives. Vesting of these awards is contingent upon the Company meeting certain total shareholder return ("TSR") levels as compared to a select peer group over the next three years. The MPRSUs cliff vest at the end of the three-year period and have a maximum potential to vest at 200% (374,444 shares) based on TSR performance. The related share-based compensation expense is determined based on the estimated fair value of the underlying shares on the date of grant and is recognized on a straight-line basis over the vesting term. The estimated fair value per share of the MPRSUs was $25.44 and was calculated using a Monte Carlo simulation model. The awards also include 187,211 performance based awards that will vest over the next three years based on the Company achieving certain clinical milestones.

During the six months ended June 30, 2018, none of the clinical milestones for the performance based RSUs awarded in 2017 or 2018 were reached.

For the six months ended June 30, 2018, 510,695 RSUs have vested and all non-vested units are expected to vest over their normal term. As of June 30, 2018, there was $25.6 million of total unrecognized compensation cost related to unvested RSUs with service-based vesting conditions. These costs are expected to be recognized over a weighted average period of three years.

Compensation Expense Related to Equity Awards

The following table summarizes information related to compensation expense recognized in the statements of operations related to the equity awards:

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	2018	2017	2018	2017
Equity compensation expense recognized in:				
Research and development expense	$2,641	$2,313	$5,698	$5,066
Selling, general and administrative expense	3,700	3,224	8,121	6,501
Total equity compensation expense	$6,341	$5,537	$13,819	$11,567

Note 8. Assets and Liabilities Measured at Fair Value

The Company’s financial assets and liabilities are measured at fair value and classified within the fair value hierarchy, which is defined as follows:

Level 1 — Quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.

Level 2 — Inputs other than quoted prices in active markets that are observable for the asset or liability, either directly or indirectly.

Level 3 — Inputs that are unobservable for the asset or liability.

A summary of the fair value of the Company’s recurring assets and liabilities aggregated by the level in the fair value hierarchy within which those measurements fall as of June 30, 2018 are identified in the following table:

(in thousands)	Level 2	Total
Assets:		
Commercial paper	$144,698	$144,698
Asset-backed securities	49,013	49,013
Corporate debt securities	285,366	285,366
Money market funds	3,081	3,081
	$482,158	$482,158

	Level 2	Level 3	Total
Liabilities:			
Contingent consideration payable	$—	$26,800	$26,800
Deferred compensation plan liability	2,731	—	2,731

$2,731 $26,800 $29,531

Explanation of Responses:

A summary of the fair value of the Company's recurring assets and liabilities aggregated by the level in the fair value hierarchy within which those measurements fall as of December 31, 2017 are identified in the following table:

(in thousands)	Level 2	Total
Assets:		
Commercial paper	$79,803	$79,803
Asset-backed securities	30,287	30,287
Corporate debt securities	199,012	199,012
Money market funds	2,598	2,598
	$311,700	$311,700

	Level 2	Level 3	Total
Liabilities:			
Contingent consideration payable	$—	$25,400	$25,400
Deferred compensation plan liability	2,258	—	2,258
	$2,258	$25,400	$27,658

The Company's Convertible Notes fall into the Level 2 category within the fair value level hierarchy. The fair value was determined using broker quotes in a non-active market for valuation. The fair value of the debt at June 30, 2018 was approximately $666.2 million.

The Company did not have any Level 3 assets as of June 30, 2018 or December 31, 2017.

Cash, Money Market Funds and Marketable Securities

The Company classifies its cash within the fair value hierarchy as Level 1 as these assets are valued using quoted prices in an active market for identical assets at the measurement date. The Company considers its investments in marketable securities as available for sale debt securities and classifies these assets and the money market funds within the fair value hierarchy as Level 2 primarily utilizing broker quotes in a non-active market for valuation of these securities. No changes in valuation techniques or inputs occurred during the six months ended June 30, 2018. No transfers of assets between Level 1 and Level 2 of the fair value measurement hierarchy occurred during the six months ended June 30, 2018.

Contingent Consideration Payable

The contingent consideration payable resulted from the acquisition of Callidus Biopharma, Inc. ("Callidus") in November 2013. The most recent valuation was determined using a probability weighted discounted cash flow valuation approach. Using this approach, expected future cash flows are calculated over the expected life of the agreement, are discounted, and then exercise scenario probabilities are applied. The valuation is performed quarterly. Gains and losses are included in the statement of operations.

The contingent consideration payable for Callidus has been classified as a Level 3 recurring liability as its valuation requires substantial judgment and estimation of factors that are not currently observable in the market. If different assumptions were used for the various inputs to the valuation approach, the estimated fair value could be significantly higher or lower than the fair value the Company determined. The Company may be required to record losses in future periods.

The following significant unobservable inputs were used in the valuation of the contingent consideration payable of Callidus for the ATB200 Pompe program:

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Explanation of Responses: 11

Contingent Consideration Liability	Fair Value as of June 30, 2018	Valuation Technique	Unobservable Input	Range
			Discount rate	11.0%
Clinical and regulatory milestones	$26.3 million	Probability weighted discounted cash flow	Probability of achievement of milestones	71.0%-100.0%
			Projected year of payments	2018-2022

Contingent consideration liabilities are remeasured to fair value each reporting period using discount rates, probabilities of payment and projected payment dates. Projected contingent payment amounts related to clinical and regulatory based milestones are discounted back to the current period using a discounted cash flow model. Increases in discount rates and the time to payment may result in lower fair value measurements. Increases or decreases in any of those inputs together, or in isolation, may result in a significantly lower or higher fair value measurement. There is no assurance that any of the conditions for the milestone payments will be met.

The following table shows the change in the balance of contingent consideration payable for the three and six months ended June 30, 2018 and 2017, respectively:

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	2018	2017	2018	2017
Balance, beginning of the period	$26,500	$274,300	25,400	269,722
Payment of contingent consideration in cash	—	(10,000)	—	(10,000)
Changes in fair value during the period, included in statement of operations	300	1,050	1,400	5,628
Balance, end of the period	$26,800	$265,350	26,800	$265,350

Deferred Compensation Plan - Investment and Liability

The Deferred Compensation Plan (the "Deferral Plan") provides certain key employees and members of the Board of Directors with an opportunity to defer the receipt of such participant’s base salary, bonus and director’s fees, as applicable. Deferral Plan assets are classified as trading securities and recorded at fair value with changes in the investment’s fair value recognized in the period they occur. The asset investments consist of market exchanged mutual funds. The Company considers its investments in marketable securities as available-for-sale and classifies these assets and related liability within the fair value hierarchy as Level 2, primarily utilizing broker quotes in a non-active market for valuation of these securities.

Note 9. Basic and Diluted Net Loss per Common Share

The following table provides a reconciliation of the numerator and denominator used in computing basic and diluted net loss attributable to common stockholders per common share:

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands, except per share amounts)	2018	2017	2018	2017
Numerator:				
Net loss attributable to common stockholders	$(61,833)	$(48,136)	$(111,751)	$(103,129)
Denominator:				

Weighted average common shares outstanding — basic and diluted	188,621,423	143,000,718	182,303,128	142,886,614

Dilutive common stock equivalents would include the dilutive effect of common stock options, convertible debt units, RSUs and warrants for common stock equivalents. Potentially dilutive common stock equivalents were excluded from the diluted earnings per share denominator for all periods because of their anti-dilutive effect.

Explanation of Responses:

The table below presents potential shares of common stock that were excluded from the computation as they were anti-dilutive using the treasury stock method:

	As of June 30,	
(in thousands)	2018	2017
Options to purchase common stock	15,869	17,275
Convertible debt	40,850	40,850
Outstanding warrants, convertible to common stock	2,657	3,110
Unvested restricted stock units	3,556	2,826
Vested restricted stock units, unissued	111	50
Total number of potentially issuable shares	63,043	64,111

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

Overview

We are a global patient-centric biotechnology company engaged in the discovery, development and commercialization of a diverse set of novel treatments for patients living with rare metabolic diseases. The cornerstone of our portfolio is migalastat HCl, (also referred to as "migalastat"), an oral precision medicine for people living with Fabry disease who have amenable genetic mutations. Migalastat is currently approved under the trade name GALAFOLD in the European Union ("EU") and Japan, with additional approvals granted and applications pending in several geographies. During the second quarter of 2018, we initiated the commercial launch of GALAFOLD in Japan for the treatment of patients, aged 16 and older, with a confirmed diagnosis of Fabry disease and an amenable mutation. GALAFOLD is the first and only oral precision medicine approved for the treatment of Fabry disease in Japan.

The lead biologics program of our pipeline is Amicus Therapeutics GAA (AT-GAA, also known as ATB200/AT2221), a novel, clinical-stage, potential best-in-class treatment paradigm for Pompe disease. Our Chaperone-Advanced Replacement Therapy ("CHART®") platform technology is leveraged to develop novel Enzyme Replacement Therapy ("ERT") products for Pompe disease, Fabry disease, and potentially future other lysosomal storage disorders ("LSDs"). We are also investigating preclinical and discovery programs in other rare diseases including cyclin-dependent kinase-like 5 ("CDKL5") deficiency. We believe that our platform technologies and our product pipeline uniquely positions us and drives our commitment to advancing and expanding a robust pipeline of cutting-edge, first- or best-in-class medicines for rare metabolic diseases.

During the first quarter of 2018, we issued 20,239,839 shares of our common stock through an underwritten offering resulting in net proceeds of $294.6 million after deducting underwriting discounts and commissions and offering expenses payable by us. We expect to use the net proceeds of the offering for investment in the United States ("U.S.") and international commercial infrastructure for migalastat HCl, investment in manufacturing capabilities for the ERT ATB200, the continued clinical development of our product candidates, research and development expenditures, clinical and pre-clinical trial expenditures, commercialization expenditures and for other general corporate purposes.

Our Strategy

Our strategy is to create, manufacture, test and deliver the highest quality medicines for people living with rare metabolic diseases through internally developed, acquired or in-licensed products and product candidates that have the potential to obsolete current treatments, provide significant benefits to patients, and be first- or best-in-class. In addition to our lead programs in Fabry and Pompe, we intend to leverage our global capabilities to develop and expand our robust pipeline, with the goal of entering clinical development with one or more programs in 2019. Since the beginning of our last fiscal year, we made significant progress toward fulfilling our vision to build a leading global biotechnology company focused on rare metabolic diseases.

Highlights of our progress in the first six months of 2018 include:

- Commercial success. In the six months ended June 30, 2018, GALAFOLD revenue totaled approximately $38.0 million. Revenue has been generated from outside the U.S., primarily in the EU.
- Regulatory progress. Received approval for migalastat in Japan and completed global regulatory submissions for migalastat in the U.S. and other key geographies. The FDA has accepted the New Drug Application ("NDA") for filing under Priority Review, and the Prescription Drug User Fee Act goal date for the FDA decision is August 13, 2018, but there is no guarantee about when the FDA will make any decision concerning the NDA, or when, if ever, FDA approval will be granted.

- Pompe clinical study. We have reported positive data from a Phase 1/2 clinical study to evaluate Pompe disease patients treated with our novel treatment paradigm AT-GAA.
- Manufacturing. Successfully scaled manufacture of Pompe biologic engineering batches to commercial scale (1,000L) with capacity plans to enable us to produce sufficient quantities to serve the entire Pompe population as quickly as possible after receipt of applicable regulatory approvals.
- Financial strength. Total cash, cash equivalents and marketable securities of $552.8 million at June 30, 2018 compared to $358.6 million at December 31, 2017. The current cash position, including proceeds from the February 2018 equity offering and expected GALAFOLD revenues, is sufficient to fund ongoing Fabry and Pompe program operations into at least 2021. Potential future business development collaborations, pipeline expansion, and investment in biologics manufacturing capabilities could impact our future capital requirements.

Our Commercial Product and Product Candidates

Migalastat for Fabry Disease

Migalastat was approved for use in the EU in May 2016 under the brand name GALAFOLD as a first-line therapy for long-term treatment of adults and adolescents, aged 16 years and older, with a confirmed diagnosis of Fabry disease and who have an amenable mutation. The approved EU label includes 348 Fabry-causing mutations, which represent up to half of all patients with Fabry disease. In the second quarter of 2018, we initiated the commercial launch of GALAFOLD in Japan. We currently have an NDA submission under Priority Review in the United States. The Prescription Drug User Fee Act goal date for the FDA decision is August 13, 2018, but there is no guarantee about when the FDA will make any decision concerning the NDA, or when, if ever, FDA approval will be granted. Approvals have also been granted in Israel, Canada, Australia, South Korea, and Switzerland, with additional applications pending in other geographies.

We have launched GALAFOLD in several European countries, including France, Germany, Italy, Spain, and the UK, on a commercial basis, as well as in select other countries through reimbursed EAPs. We have been granted pricing and reimbursement in 19 countries. We plan to continue to launch GALAFOLD in additional countries during 2018.

As an orally administered monotherapy, migalastat is designed to bind to and stabilize an endogenous alpha-galactosidase A (“alpha-Gal A”) enzyme in those patients with genetic mutations identified as amenable in a GLP cell-based amenability assay. Migalastat is an oral precision medicine intended to treat Fabry disease in patients who have amenable genetic mutations and, at this time, it is not intended for concomitant use with ERT.

Patients with Fabry disease have an inherited deficiency of the alpha-Gal A enzyme that would normally degrade the lipid substrate globotriaosylceramide in the lysosome. Genetic mutations that cause changes in the amino acid sequence of alpha-Gal A result in an unstable enzyme that does not efficiently fold into its correct three-dimensional shape and cannot be trafficked properly in the cell, even if it has the potential for biological activity. Migalastat is an oral small molecule pharmacological chaperone that is designed to bind to and stabilize a patient’s own endogenous target protein. This is considered a precision medicine because migalastat targets only patients with GLA mutations or variants amenable to migalastat.

We have completed two Phase 3 global registration studies of migalastat monotherapy. We have reported Phase 3 data in both treatment-naïve patients (“Study 011”) and ERT-switch patients (“Study 012”). Results from these studies have shown that treatment with migalastat results in reductions in disease substrate, stability of kidney function, reductions in cardiac mass, and improvement in gastrointestinal symptoms in patients with GLA mutations or variants amenable to migalastat in a validated GLP amenability assay.

Next-Generation Therapies for Fabry Disease

We are committed to continued innovation for all people living with Fabry disease. For people living with Fabry disease who have non-amenable mutations or variants, which are not suitable for migalastat as a monotherapy, our strategy is to advance next-generation therapies such as our proprietary Fabry-ERT co-formulated with migalastat or other innovative technologies that we continue to evaluate.

We are leveraging our CHART® technology and advanced biologics capabilities to move forward with a proprietary Fabry ERT for co-formulation with migalastat. Master cell banking has been completed, process development work has commenced, and initial preclinical studies have been completed to potentially advance this novel co-formulation toward the clinic in 2019.

Novel ERT for Pompe Disease

We are leveraging our biologics capabilities and CHART® platform to develop Amicus Therapeutics GAA (AT-GAA, also known as ATB200/AT2221), a novel treatment paradigm for Pompe disease. AT-GAA consists of a uniquely engineered rhGAA enzyme, ATB200, with an optimized carbohydrate structure to enhance lysosomal uptake, administered in combination with a pharmacological chaperone, AT2221, to improve activity and stability. We acquired ATB200 as well as our enzyme targeting technology through our purchase of Callidus. ATB200 is our first biologic to enter clinical development.

The pharmacological chaperone, AT2221 is not an active ingredient that contributes directly to GAA substrate reduction but instead acts to stabilize ATB200. The small molecule pharmacological chaperone AT2221 binds and stabilizes ATB200 to improve the uptake of active enzyme in key disease-relevant tissues, resulting in increased clearance of accumulated substrate, glycogen.

In preclinical studies, AT-GAA demonstrated greater tissue enzyme levels and further substrate reduction compared to the currently approved ERT for Pompe disease (alglucosidase alfa).

We are engaged in ongoing collaborative discussions with U.S. and EU regulators regarding a registration-directed study for approval, manufacturing activities, and the best and fastest pathway forward for AT-GAA. A scientific advice meeting with the European Medicines Agency (“EMA”) was held in the second quarter of 2018. The scientific advice authorities from the EMA indicated that the current clinical package is not sufficient for a Conditional Marketing Authorization Application at this time. We intend to continue a dialogue on a potential pathway for conditional approval with the EMA authorities in 2019. In the U.S., ongoing interactions for this program include a Type C meeting scheduled to occur in the third quarter of 2018. We expect to provide an FDA update following the receipt of written minutes from this meeting. We continue to believe that the evolving regulatory path will include a series of further iterative discussions with regulators as the program advances and as additional data is collected.

Throughout 2017, we reported a cascade of interim data from a Phase 1/2 clinical study, ATB200-02, to investigate our novel Pompe treatment paradigm in Pompe patients. The primary objective was to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics (“PD”) of AT-GAA for an 18-week primary treatment period followed by a long-term extension. The three patient cohorts, enrolling 20 total patients across all cohorts, are ambulatory ERT-switch patients (Cohort 1), non-ambulatory ERT-switch patients (Cohort 2), and ERT-naïve patients (Cohort 3).

As of our interim analysis reported in October 2017, patients who completed six months of treatment with AT-GAA showed improvements in the six-minute walk test ("6MWT") distance and other measures of motor function, stability or increases in forced vital capacity ("FVC"), and further reductions in biomarkers of muscle damage and disease substrate, with consistent results reported in initial patients who completed nine months of treatment.

On February 8, 2018 we reported additional interim data from our clinical study ATB200-02 at the 14th Annual WORLD Symposium. Highlights included safety and tolerability data in all 20 patients (maximum of 20+ months of treatment) as well as PD data (muscle damage biomarker and disease substrate biomarker) for all 20 patients (15 ERT-switch patients and 5 ERT-naïve patients). To date, adverse events have been generally mild and transient. AT-GAA has resulted in a low rate of infusion-associated reactions (IARs) following 550+ infusions (three events of IARs in two patients; < 1% of all 550+ infusions with an IAR). The clinical pharmacokinetic profile has been consistent with previously reported preclinical data. Treatment with AT-GAA resulted in persistent and durable reductions in creatine kinase and urine hexose tetrasaccharide across all patient cohorts out to month 12.

As of the last interim analysis in February 2018, data on functional outcomes are available for 19 of the 20 patients enrolled (one patient dropped out of the extension study due to travel burden and family considerations). Muscle function improved in 16 of 19 patients at month 9. Muscle function improved in 10 out of 10 patients with available data at month 12. Mean 6MWT improved in both ERT-naïve and ERT-switch patients with continued benefit observed out to month 12. All 5 ERT-naïve patients showed increases in 6MWT distance at all time points out to month 12. The ERT-naïve patients showed mean increases of 41.8 meters at month 6 (n=5), 63.5 meters at month 9 (n=5), and 86.8 meters at month 12 (n=2). Of the 10 ERT-switch patients, 8 patients showed increases in 6MWT distance and two patients showed decreases at month 9. All eight of the ERT-switch patients with available data at month 12 showed increases in 6MWT distance. The ERT-switch patients showed mean increases of 23.9 meters at month 6 (n=10), 24.5 meters at month 9 (n=10), and 57.4 meters at month 12 (n=8). Other motor function tests generally showed mean improvements consistent with 6MWT distance. Three of the four non-ambulatory ERT-switch patients showed improvements in upper extremity strength (which includes elbow and shoulder) from baseline to month 9, as measured by quantitative muscle testing and manual muscle testing. Pulmonary function improved in ERT-naïve patients and was generally stable in ERT-switch patients. In ERT-naïve patients, mean absolute change in FVC was +4.2% at month 6 (n=5), +6.2% at month 9 (n=5), and +6.0% at month 12 (n=2). In ERT-switch patients

mean absolute change in FVC was -1.3% at month 6 (n=9), -1.7% at month 9 (n=9), and -3.1% at month 12 (n=7). Overall, other pulmonary tests of maximal inspiratory pressure, a measure of inhalation, and maximal expiratory pressure, a measure of exhalation, were stable or increased in both ERT-naïve and ERT-switch patients.

CDKL5

We are researching a potential first-in-class protein replacement therapy approach for CDKL5 deficiency in preclinical studies. CDKL5 is a gene on the X-chromosome encoding the CDKL5 protein that regulates the expression of several essential proteins for normal brain development. Genetic mutations in the CDKL5 gene result in CDKL5 protein deficiency and the disorder manifests clinically as persistent seizures starting in infancy, followed by severe impairment in neurological development. Most children affected by CDKL5 deficiency cannot walk or care for themselves and may also suffer from scoliosis, visual impairment, sensory issues, and gastrointestinal complications.

Strategic Alliances and Arrangements

We will continue to evaluate business development opportunities as appropriate that build stockholder value and provide us with access to the financial, technical, clinical, and commercial resources necessary to develop and market pharmacological chaperone therapeutics, ERTs, and other technologies or products with a focus on rare metabolic diseases. We are exploring potential collaborations, alliances, and other business development opportunities on a regular basis. These opportunities may include the acquisition of preclinical-stage, clinical-stage or marketed products so long as such transactions are consistent with our strategic plan to develop and provide therapies to patients living with rare and orphan diseases and support our continued transformation from a development-stage company into a commercial biotechnology company.

Consolidated Results of Operations

Three Months Ended June 30, 2018 compared to June 30, 2017

The following table provides selected financial information for the Company:

	Three Months Ended June 30,		
(in thousands)	2018	2017	Change
Net product sales	$21,309	$7,158	$14,151
Cost of goods sold	3,135	1,061	2,074
Cost of goods sold as a percentage of net product sales	14.7 %	14.8 %	(0.1)%
Operating expenses:			
Research and development	34,660	31,985	2,675
Selling, general and administrative	29,172	19,311	9,861
Changes in fair value of contingent consideration payable	300	1,050	(750)
Depreciation	973	812	161
Other income (expense):			
Interest income	2,913	753	2,160
Interest expense	(4,560)	(4,179)	(381)
Change in fair value of derivatives	(7,600)	—	(7,600)
Other (expense) income	(5,316)	2,400	(7,716)
Income tax benefit (expense)	(339)	(49)	(290)
Net loss attributable to common stockholders	$(61,833)	$(48,136)	$(13,697)

Net Product Sales. Net product sales increased $14.2 million during the three months ended June 30, 2018 compared to the same period in the prior year. GALAFOLD was approved for sale in the EU in May 2016 and has been approved for pricing and reimbursement in 19 countries, as well as in select other European markets through reimbursed EAPs. The increase in revenue was related to the increase in the number of markets where we had obtained pricing and reimbursements and the corresponding increase in the number of patients being treated with GALAFOLD.

Cost of Goods Sold. Cost of goods sold includes manufacturing costs as well as royalties associated with sales of our product. Cost of goods sold as a percentage of net product sales was 14.7% during the three months ended June 30, 2018 compared to 14.8% during the same period in the prior year.

Research and Development Expense. The following table summarizes our principal product development programs, including the related stages of development, for each product candidate in development, and the out-of-pocket, third party expenses incurred with respect to each product candidate:

(in thousands)	Three Months Ended June 30,	
Projects	2018	2017
Third party direct project expenses		
Migalastat (Fabry Disease)	$3,726	$2,529
AT-GAA (Pompe Disease)	9,538	10,206
SD-101 (EB-Epidermolysis Bullosa)	—	2,337
Pre-clinical programs	142	110
Total third party direct project expenses	13,406	15,182
Other project costs		
Personnel costs	13,967	11,270
Other costs	7,287	5,533
Total other project costs	21,254	16,803
Total research and development costs	$34,660	$31,985

The increase in research and development costs was primarily due to increases in personnel and other costs with the advancement and enrollment of clinical studies and investments in manufacturing. The decrease in the EB program was due to the results announced in September 2017 that the study did not meet the primary or secondary endpoints in participants. The decrease in the Pompe program was due to the timing of manufacturing of ATB200 large scale batches.

Selling, General and Administrative Expense. Selling, general and administrative increased $9.9 million primarily due to the expanded geographic scope of the ongoing commercial launch of GALAFOLD.

Changes in Fair Value of Contingent Consideration Payable. The change in the fair value of the contingent consideration payable of $0.8 million resulted from a decrease in the Scioderm, Inc. (“Scioderm”) contingent consideration of $0.7 million and decrease in the Callidus contingent consideration of $0.1 million. The fair value and change in fair value are impacted by updates to the estimated probability of achievement, assumed timing of milestones and adjustments to the discount periods and rates. The decrease in Scioderm contingent consideration was due to the results announced in September 2017 that the study did not meet the primary or secondary endpoints in participants, and, as a result, the contingent consideration is no longer payable.

Change in Fair Value of Derivatives. Subsequent to the underwritten public offering on February 15, 2018, we did not have sufficient unissued authorized shares to cover a conversion of the Convertible Notes. The fair value of the derivative liability for the conversion feature and derivative asset for the Capped Call Confirmations at February 15, 2018 was determined to be $507.4 million and $13.6 million, respectively, of which the portion that was determined to not be able to be net share settled was recorded with a corresponding impact to additional-paid-in-capital. Following the approval by the Company's stockholders on June 7, 2018, to increase the authorized shares of common stock to 500,000,000, we now have sufficient unissued authorized shares to cover a conversion of the Convertible Notes. As a result, the derivative liability and derivative asset were reclassified into additional-paid-in-capital. Subsequent changes to fair value of the derivatives were recorded through earnings on our consolidated statements of operations resulting in a change in fair value of derivatives for the three months ended June 30, 2018 of $7.6 million.

Other Expense. The $7.7 million increase in other expense was primarily due to unrealized losses on foreign exchange transactions.

Income Tax Benefit (Expense). The income tax expense is related to the provision during the three months ended June 30, 2018. We are subject to income taxes in the United States, although currently not a tax payer, and in various foreign jurisdictions, and our foreign tax liabilities are largely dependent upon the distribution of pre-tax earnings among these different jurisdictions.

Six Months Ended June 30, 2018 compared to June 30, 2017

The following table provides selected financial information for the Company:

	Six Months Ended June 30,		
(in thousands)	2018	2017	Change
Net product sales	$38,005	$11,327	26,678
Cost of goods sold	5,750	1,836	3,914
Cost of goods sold as a percentage of net product sales	15.1 %	16.2 %	(1.1)%
Operating expenses:			
Research and development	75,458	62,861	12,597
Selling, general and administrative	56,568	38,443	18,125
Changes in fair value of contingent consideration payable	1,400	5,628	(4,228)
Depreciation	1,942	1,636	306
Other income (expense):			
Interest income	4,650	1,512	3,138
Interest expense	(9,048)	(8,469)	(579)
Change in fair value of derivatives	(2,739)	—	(2,739)
Other (expense) income	(2,554)	3,010	(5,564)
Income tax benefit (expense)	1,053	(105)	1,158
Net loss attributable to common stockholders	$(111,751)	$(103,129)	$(8,622)

Net Product Sales. Net product sales increased $26.7 million during the six months ended June 30, 2018 compared to the same period in the prior year. GALAFOLD was approved for sale in the EU in May 2016 and has been approved for pricing and reimbursement in 19 countries, as well as in select other European markets through reimbursed EAPs. The increase in revenue was related to the increase in the number of markets where we had obtained pricing and reimbursements and the corresponding increase in the number of patients being treated with GALAFOLD.

Cost of Goods Sold. Cost of goods sold includes manufacturing costs as well as royalties associated with sales of our product. Cost of goods sold as a percentage of net product sales decreased to 15.1% during the six months ended June 30, 2018 compared to 16.2% during the same period in the prior year primarily due to an increase in the proportion of sales in countries subject to a lower royalty burden.

Research and Development Expense. The following table summarizes our principal product development programs, including the related stages of development, for each product candidate in development, and the out-of-pocket, third party expenses incurred with respect to each product candidate:

(in thousands)	Six Months Ended June 30,	
Projects	2018	2017
Third party direct project expenses		
Migalastat (Fabry Disease)	$7,434	$5,379
AT-GAA (Pompe Disease)	25,052	19,138
SD-101 (EB-Epidermolysis Bullosa)	—	5,764
Pre-clinical programs	800	238
Total third party direct project expenses	33,286	30,519
Other project costs		
Personnel costs	28,916	22,752
Other costs	13,256	9,590
Total other project costs	42,172	32,342

Total research and development costs	$75,458	$62,861

Explanation of Responses:

The increase in research and development costs was primarily due to personnel and other costs and increases in clinical research and manufacturing costs with the advancement and enrollment of clinical studies and investments in manufacturing. The decrease in the EB program was due to the results announced in September 2017 that the study did not meet the primary or secondary endpoints in participants.

Selling, General and Administrative Expense. Selling, general and administrative increased $18.1 million primarily due to the expanded geographic scope of the ongoing commercial launch of GALAFOLD.

Changes in Fair Value of Contingent Consideration Payable. The change in the fair value of the contingent consideration payable of $4.2 million resulted from a decrease in the Scioderm contingent consideration of $4.6 million offset by an increase in the Callidus contingent consideration of $0.4 million. The fair value and change in fair value are impacted by updates to the estimated probability of achievement, assumed timing of milestones and adjustments to the discount periods and rates. The decrease in the Scioderm contingent consideration was due to the results announced in September 2017 that the study did not meet the primary or secondary endpoints in participants, and, as a result, the contingent consideration is no longer payable.

Change in Fair Value of Derivatives. Subsequent to the underwritten public offering on February 15, 2018, we did not have sufficient unissued authorized shares to cover a conversion of the Convertible Notes. The fair value of the derivative liability for the conversion feature and derivative asset for the Capped Call Confirmations at February 15, 2018 was determined to be $507.4 million and $13.6 million, respectively, of which the portion that was determined to not be able to be net share settled was recorded with a corresponding impact to additional-paid-in-capital. Following to the approval by the Company's stockholders on June 7, 2018, to increase the authorized shares of common stock to 500,000,000, we now have sufficient unissued authorized shares to cover a conversion of the Convertible Notes. As a result, the derivative liability and derivative asset were reclassified into additional-paid-in-capital. Subsequent changes to fair value of the derivatives were recorded through earnings on our consolidated statements of operations resulting in a change in fair value of derivatives for the six months ended June 30, 2018 of $2.7 million.

Other Expense. The $5.6 million increase in other expense was primarily due to unrealized losses on foreign exchange transactions.

Income Tax Benefit (Expense). The income tax benefit related to a discrete tax item that was recorded during the six months ended June 30, 2018. We are subject to income taxes in the United States, although currently not a tax payer, and in various foreign jurisdictions, and our foreign tax liabilities are largely dependent upon the distribution of pre-tax earnings among these different jurisdictions.

Liquidity and Capital Resources

As a result of our significant research and development expenditures, as well as expenditures to build a commercial organization to support the launch of GALAFOLD, we have not been profitable and have generated operating losses since we were incorporated in 2002. We have historically funded our operations principally through the issuance and sale of stock, collaborations, debt financings, grants and non-refundable license fees.

Source of Liquidity

During the first quarter of 2018, we issued, through an underwritten offering, 20,239,839 shares of our common stock resulting in net proceeds of $294.6 million after deducting underwriting discounts and commissions and offering expenses payable by us. We expect to use the net proceeds of the offering for investment in the U.S. and international

commercial infrastructure for migalastat HCl, investment in manufacturing capabilities for ATB200, the continued clinical development of our product candidates, research and development expenditures, clinical and pre-clinical trial expenditures, commercialization expenditures and for other general corporate purposes.

Cash flow discussion

As of June 30, 2018, we had cash, cash equivalents and marketable securities of $552.8 million. We invest cash in excess of our immediate requirements with regard to liquidity and capital preservation in a variety of interest-bearing instruments, including obligations of U.S. government agencies and money market accounts. Wherever possible, we seek to minimize the potential effects of concentration and degrees of risk. Although we maintain cash balances with financial institutions in excess of insured limits, we do not anticipate any losses with respect to such cash balances. For more details on the cash, cash equivalents and marketable securities, refer to "—Note 3. Cash, Cash Equivalents, Marketable Securities and Restricted Cash," in our Notes to Consolidated Financial Statements.

Net Cash Used in Operating Activities

Net cash used in operations for the six months ended June 30, 2018 was $106.5 million. The components of net cash used in operations included the net loss for the six months ended June 30, 2018 of $111.8 million and the net increase in operating assets of $5.7 million. The change in operating assets was primarily due to increases in accounts receivable by$6.0 million and inventory of $3.4 million due to commercial sales of GALAFOLD, partially offset by a decrease in prepaid and other current assets of $4.6 million for spending to support commercial activities for GALAFOLD launch. The net cash used in operations was also impacted by a decrease in accounts payable and accrued expenses of $11.8 million, mainly related to program expenses and support for the commercial launch of GALAFOLD, and a decrease in deferred reimbursement of $5.0 million due to payment of a milestone.

Net cash used in operations for the six months ended June 30, 2017 was $91.8 million. The components of net cash used in operations included the net loss for the six months ended June 30, 2017 of $103.1 million and the increase in operating assets of $5.2 million. The increase in operating assets was primarily due to increases in accounts receivable of $2.2 million and inventories by $0.4 million due to an increase in commercial sales. The net cash used in operations was partially offset by an increase in operating liabilities of $3.8 million for the increase of $4.3 million in accounts payable and accrued expenses related to program expenses and support for the commercial launch of GALAFOLD.

Net Cash Used in Investing Activities

Net cash used in investing activities for the six months ended June 30, 2018 was $171.9 million. Our investing activities have consisted primarily of purchases and sales and maturities of investments and capital expenditures. Net cash used in investing activities reflects $380.2 million for the purchase of marketable securities, and $1.9 million for the acquisition of property and equipment, partially offset by $210.2 million for the sale and redemption of marketable securities.

Net cash used in investing activities for the six months ended June 30, 2017 was $48.9 million. Our investing activities have consisted primarily of purchases and sales and maturities of investments and capital expenditures. Net cash used in investing activities reflects $184.5 million for the purchase of marketable securities, and $2.3 million for the acquisition of property and equipment, partially offset by $137.9 million for the sale and redemption of marketable securities.

Net Cash Provided by/ Used in Financing Activities

Net cash provided by financing activities for the six months ended June 30, 2018 was $303.6 million. Net cash provided by financing activities primarily reflects $294.6 million from the issuance of common stock, net of issuance costs, and $11.2 million from the exercise of stock options and warrants, partially offset by $2.0 million from the purchase of vested restricted stock units.
Net cash used in financing activities for the six months ended June 30, 2017 was $9.6 million. Net cash used in financing activities primarily reflects $10.0 million in payment for contingent consideration, and $1.0 million from the purchase of vested of restricted stock units, partially offset by $1.6 million from the exercise of stock options.

Funding Requirements

We expect to incur losses from operations for the foreseeable future primarily due to research and development expenses, including expenses related to conducting clinical trials. Our future capital requirements will depend on a number of factors, including:

- the progress and results of our clinical trials of our drug candidates;
- the cost of manufacturing drug supply for our clinical and preclinical studies, including the cost of manufacturing Pompe ERT;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our product candidates including those testing the use of pharmacological chaperones co-formulated and co-administered with ERT and for the treatment of LSDs;
- the future results of on-going preclinical research and subsequent clinical trials for CDKL5, including our ability to obtain regulatory approvals and commercialize CDKL5 and obtain market acceptance for CDKL5;

- the costs, timing and outcome of regulatory review of our product candidates;
- the number and development requirements of other product candidates that we pursue;
- the costs of commercialization activities, including product marketing, sales and distribution;
- the emergence of competing technologies and other adverse market developments;
- our ability to obtain reimbursement for migalastat HCl;
- our ability to obtain market acceptance of migalastat HCl;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims;
- the extent to which we acquire or invest in businesses, products and technologies;
- our ability to successfully integrate our acquired products and technologies into our business, including the possibility that the expected benefits of the transactions will not be fully realized by us or may take longer to realize than expected; and
- our ability to establish collaborations and obtain milestone, royalty or other payments from any such collaborators.

While we have generated revenue from product sales in 2018, in the absence of additional funding, we expect our continuing operating losses to result in increases in our cash used in operations over the next several quarters and years. We may seek additional funding through public or private financings of debt or equity. We believe that our current cash position, including proceeds from the recent equity offering and expected GALAFOLD revenues, is sufficient to fund ongoing Fabry and Pompe program operations into at least 2021. Potential future business development collaborations, pipeline expansion, and investment in biologics manufacturing capabilities could impact our future capital requirements.

Financial Uncertainties Related to Potential Future Payments

Milestone Payments / Royalties

We acquired exclusive worldwide patent rights to develop and commercialize migalastat and other pharmacological chaperones for the prevention or treatment of human diseases or clinical conditions by increasing the activity of wild-type and mutant enzymes pursuant to a license agreement with Mount Sinai School of Medicine (“MSSM”). This agreement expires upon expiration of the last of the licensed patent rights, which will be in 2018 in the U.S. and 2019 in Europe and Japan for monotherapy. If we develop a product for combination therapy of specific pharmacological chaperone such as migalastat plus an ERT for certain LSDs such as Fabry disease and a patent issues from the pending MSSM applications covering such a combination therapy(ies), expiration for the combination product(s) will be 2024.

In November 2013, we entered into the Revised Agreement (the "Revised Agreement") with GlaxoSmithKline (“GSK”), pursuant to which we have obtained global rights to develop and commercialize migalastat as a monotherapy and in combination with ERT for Fabry disease. The Revised Agreement amends and replaces in its entirety the earlier agreement entered into between us and GSK in July 2012 (the "Original Collaboration Agreement"). Under the terms of the Revised Agreement, there was no upfront payment from us to GSK. For migalastat monotherapy, GSK is eligible to receive post-approval and sales-based milestones up to $40 million, as well as tiered royalties in the mid-teens in eight major markets outside the United States. In addition, because we reacquired worldwide rights to migalastat, we are no longer eligible to receive any milestones or royalties we would have been eligible to receive under the Original Collaboration Agreement.

Under our license agreements, if we owe royalties on net sales for one of our products to more than one of the above licensors, we have the right to reduce the royalties owed to one licensor for royalties paid to another. The amount of royalties to be offset is generally limited in each license and can vary under each agreement. For the six months ended June 30, 2018, under the license agreements we paid $3.9 million in royalties and $5.0 million in sales-based

milestones.

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Explanation of Responses: 31

Critical Accounting Policies and Significant Judgments

The discussion and analysis of our financial condition and results of operations are based on our financial statements, which we have prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments, including those described in greater detail below. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

There were no significant changes during the six months ended June 30, 2018 to the items that we disclosed as our significant accounting policies and estimates described in "—Note 2. Summary of Significant Accounting Policies" to the Company's financial statements as contained in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2017, except as it relates to the adoption of ASU 2014-09, Revenue from Contracts with Customers (Topic 606), which is described below.

Revenue Recognition

Our net product sales consist of sales of GALAFOLD for the treatment of Fabry disease primarily in the EU. We have recorded revenue on sales where GALAFOLD is available either on a commercial basis or through a reimbursed EAP. Orders for GALAFOLD are generally received from pharmacies and the ultimate payor is typically a government authority.

We recognize revenue when our performance obligation with our customers have been satisfied, which occurs at a point in time when the pharmacies or distributors obtain control of GALAFOLD. The transaction price is determined based on fixed consideration in our customer contracts and is recorded net of estimates for variable consideration, which are third party discounts and rebates. The identified variable consideration is recorded as a reduction of revenue at the time revenues from sales of GALAFOLD are recognized. We recognize revenue to the extent that it is probable that a significant revenue reversal will not occur in a future period. These estimates may differ from actual consideration amount received and we evaluate these estimates each reporting period to reflect known changes in factors.

We elected the portfolio approach practical expedient in applying ASC Topic 606 to our identified revenue streams. Contracts within each revenue stream have similar characteristics and we believe the results of this approach would not differ materially than if we applied ASC Topic 606 to each individual contract.

Recent Accounting Pronouncements

Please refer to "—Note 2. Summary of Significant Accounting Policies," in our Notes to Consolidated Financial Statements.

ITEM 3. Quantitative and Qualitative Disclosures about Market Risk

Market risk is the risk of change in fair value of a financial instrument due to changes in interest rates, equity prices, creditworthiness, financing, exchange rates or other factors. Our primary market risk exposure relates to changes in interest rates in our cash, cash equivalents and marketable securities. We place our investments in high-quality

financial instruments, primarily money market funds, corporate debt securities, asset backed securities and U.S. government agency notes with maturities of less than one year, which we believe are subject to limited interest rate and credit risk. The securities in our investment portfolio are not leveraged, are classified as available-for-sale and, due to the short-term nature, are subject to minimal interest rate risk. We believe that a 1% (100 basis points) change in average interest rates would either increase or decrease the market value of our investment portfolio by $2.3 million as of June 30, 2018. We currently do not hedge interest rate exposure and consistent with our investment policy, we do not use derivative financial instruments in our investment portfolio. Our outstanding debt has a fixed interest rate and therefore, we have no exposure to interest rate fluctuations.

We have operated primarily in the U.S. with international operations increasing since the last quarter of 2015. We do conduct some clinical activities with vendors outside the U.S. While most expenses are paid in U.S. dollars, we now have increased transactions of expenses and cash flows in foreign currencies that are exposed to changes in foreign currency rates.

For information regarding our exposure to certain market risks, see Item 7A, Quantitative and Qualitative Disclosures About Market Risk, in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017. There have been no material changes in our financial instrument portfolio or market risk exposures since our fiscal year ended December 31, 2017.

Explanation of Responses: 33

ITEM 4. CONTROLS AND PROCEDURES

As of the end of the period covered by this Quarterly Report on Form 10-Q, an evaluation of the effectiveness of our disclosure controls and procedures (pursuant to Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”) was carried out under the supervision of our Principal Executive Officer and Principal Financial Officer, with the participation of our management. Based on that evaluation, the Principal Executive Officer and the Principal Financial Officer concluded that, as of the end of such period, our disclosure controls and procedures are effective in recording, processing, summarizing and reporting, on a timely basis, information required to be disclosed by us in the reports that we file or submit under the Exchange Act and are effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our Principal Executive Officer and Principal Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

During the fiscal quarter covered by this report, there has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the last fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None.

ITEM 1A. RISK FACTORS

There have been no material changes to the risk factors previously disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

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Explanation of Responses: 35

ITEM 6. EXHIBITS

Exhibit Number	Description
3.1	Certificate of Amendment to the Company's Restated Articles of Incorporation (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on June 8, 2018)
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14 and 15d-14 promulgated pursuant to the Securities Exchange Act of 1934, as amended
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14 and 15d-14 promulgated pursuant to the Securities Exchange Act of 1934, as amended
32.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101	The following financial information from this Quarterly Report on Form 10-Q for the six months ended June 30, 2018, formatted in XBRL (Extensible Business Reporting Language) and filed electronically herewith: (i) the Consolidated Balance Sheets; (ii) the Consolidated Statements of Operations; (iii) the Consolidated Statements of Comprehensive Loss; (iv) the Consolidated Statements of Cash Flows; (v) and the Notes to the Consolidated Financial Statements

SIGNATURES

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

AMICUS THERAPEUTICS, INC.

Date: August 7, 2018 By: /s/ John F. Crowley
John F. Crowley
Chairman and Chief Executive Officer
(Principal Executive Officer)

Date: August 7, 2018 By: /s/ William D. Baird III
William D. Baird III
Chief Financial Officer
(Principal Financial Officer)