APPLIED GENETIC TECHNOLOGIES CORP
Form 424B4
March 27, 2014
Table of Contents

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Registration File No. 333-193309

PROSPECTUS

4,166,667 Shares

Common Stock

Applied Genetic Technologies Corporation

March 26, 2014.

This is the initial public offering of the common stock of Applied Genetic Technologies Corporation. The initial public offering price is $12.00 per share.

We have granted the underwriters the option to purchase up to 625,000 additional shares of common stock to cover over-allotments.

Our shares of common stock have been approved for listing on the NASDAQ Global Market under the symbol AGTC.

Investing in our common stock involves risks. See Risk Factors beginning on page 12 of this prospectus.

We are an emerging growth company as that term is used in the Jumpstart Our Business Startups Act of 2012 and, as such, we have elected to comply with certain reduced public company reporting requirements for this prospectus and future filings.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed on the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

	Per share	Total
Initial public offering price	$ 12.00	$ 50,000,004
Underwriting discounts and commissions (1)	$ 0.84	$ 3,500,000

Proceeds to AGTC (before expenses)	$ 11.16	$ 46,500,004

(1) We refer you to Underwriting beginning on page 160 of this prospectus for additional information regarding total underwriter compensation. Certain of our existing stockholders have agreed to purchase an aggregate of $6.0 million in shares of our common stock in this offering at the initial public offering price.

The underwriters expect to deliver the shares to purchasers on or about April 1, 2014 through the book-entry facilities of The Depository Trust Company.

BMO Capital Markets Wedbush PacGrow Life Sciences

Cantor Fitzgerald & Co. Roth Capital Partners

Table of Contents

Table of Contents

PROSPECTUS SUMMARY	1
RISK FACTORS	12
CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS	55
USE OF PROCEEDS	56
DIVIDEND POLICY	57
CAPITALIZATION	58
DILUTION	59
SELECTED FINANCIAL DATA	61
MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	62
OUR BUSINESS	85
MANAGEMENT	126
EXECUTIVE COMPENSATION	133
RELATED PERSON TRANSACTIONS	144
PRINCIPAL STOCKHOLDERS	147
DESCRIPTION OF CAPITAL STOCK	150
SHARES ELIGIBLE FOR FUTURE SALE	153
MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS	156
UNDERWRITING	160
LEGAL MATTERS	167
EXPERTS	167
WHERE YOU CAN FIND MORE INFORMATION	167
INDEX TO FINANCIAL STATEMENTS	F-1

You should rely only on the information contained in this prospectus and any free writing prospectus prepared by us or on our behalf or to which we have referred you. We and the underwriters have not authorized anyone to provide you with information that is different. We and the underwriters are offering to sell shares of our common stock, and seeking offers to buy shares of our common stock, only in jurisdictions where such offers and sales are permitted. Regardless of the time of delivery of this prospectus or any free writing prospectus or any sale of our common stock, the information in this prospectus is accurate only as of the date of this prospectus, and the information in any free writing prospectus that we may provide you in connection with this offering is accurate only as of the date of that free writing prospectus. Our business, financial condition, results of operations and future growth prospects may have changed since those dates.

Until April 20, 2014, 25 days after the date of this prospectus, all dealers that buy, sell or trade our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This requirement is in addition to the dealer s obligation to deliver a prospectus when acting as an underwriter and with respect to unsold allotments or subscriptions.

For investors outside the United States: Neither we nor any of the underwriters have taken any action to permit a public offering of the shares of our common stock or the possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus and any free writing prospectus outside of the United States.

Estimates in this prospectus of the patient populations for the diseases that we are targeting are based on published estimates of the rates of incidence of the diseases from scientific and general publications and research, surveys and studies conducted by third parties that we consider to be reliable, although such publications do not guarantee the accuracy or completeness of such information. We assume populations of approximately 300 million persons in the United States and approximately 500 million persons in Europe.

Table of Contents

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. You should read the following summary together with the more detailed information appearing in this prospectus, including our financial statements and related notes and the risk factors beginning on page 12 before deciding whether to purchase shares of our common stock. Unless the context otherwise requires, we use the terms AGTC, Company, we, us and our in this prospectus to refer to Applied Genetic Technologies Corporation.

Overview

We are a clinical-stage biotechnology company that uses our proprietary gene therapy platform to develop products designed to transform the lives of patients with severe inherited orphan diseases in ophthalmology. Our lead product candidates, which are each in the preclinical stage, focus on rare diseases of the eye, caused by mutations in single genes, that significantly affect visual function and currently lack effective medical treatments. We have also obtained preliminary evidence of the safety and efficacy of our gene therapy approach in clinical-stage programs involving other diseases outside our current area of focus that we believe provide proof of concept for our gene therapy platform.

Our gene therapy approach uses a viral vector to deliver a functional copy of a gene to the patient s own cells through a variety of delivery methods. A viral vector is a virus that has been modified to carry a gene and deliver it to a cell. Our viral vectors utilize a modified version of a non-replicating strain of virus known as an adeno-associated virus, or AAV, which is incapable of causing disease in humans. When an AAV vector containing a functional copy of a gene is administered, the functional genetic material resides in the nucleus of the patient s cell, providing safe, sustained expression of the therapeutic protein to treat the disease without modifying the existing DNA of the patient.

We have developed extensive internal expertise in viral vector design, delivery and manufacturing that is supported by a broad intellectual property estate. Our proprietary AAV vector manufacturing process is both reproducible and scalable. We have assembled an experienced management team and a world-class group of scientific advisors, and we have strong collaborative relationships with key opinion leaders in the field of gene therapy. Combining these attributes, we have built a gene therapy platform that we believe will provide patients with treatments that may have life-long clinical benefits, potentially based on a one-time therapeutic administration.

Our product pipeline

Our lead product candidates are designed to treat:

X-linked retinoschisis, or XLRS. XLRS is an inherited retinal disease caused by mutations in the RS1 gene, which encodes the retinoschisin protein. It is characterized by abnormal splitting of the layers of the retina, resulting in poor visual acuity in young boys, which can progress to legal blindness in adult men. In preclinical studies, treatment by injection of our XLRS product candidate in mice improved responses to light in the retina and visual acuity. In late 2014, we plan to submit an Investigational New Drug Application, or IND, to the United States Food and Drug Administration, or FDA, and to initiate a Phase 1/2 clinical trial in XLRS, with initial clinical data expected in mid-2015.

Achromatopsia, or ACHM. ACHM is an inherited retinal disease, which is present from birth and is characterized by the lack of cone photoreceptor function. The condition results in markedly reduced visual acuity, light sensitivity, day blindness and complete loss of color discrimination. Best-corrected visual acuity in persons affected by ACHM, even under subdued light conditions, is usually about 20/200, a level at which people are considered legally blind. Preclinical studies in both mouse and dog models of our

Table of Contents

ACHM product candidate have shown the ability to restore photoreceptor function, improve visual acuity and mitigate light sensitivity and day blindness. In early 2015, we plan to submit an IND and to initiate a Phase 1/2 clinical trial in one form of ACHM, with initial clinical data expected in late 2015.

X-linked retinitis pigmentosa, or XLRP. XLRP is an inherited retinal dystrophy characterized by the progressive loss of vision, one form of which is caused by mutations in the RPGR gene, which encodes a protein essential for normal vision. It is commonly first observed in young men, who notice problems with vision under low light conditions, or night blindness, followed by tunnel vision, leading to poor central vision and eventual total blindness. A preclinical study in a dog model of XLRP caused by mutations in the RPGR gene demonstrated a delay in the rate of disease progression in dogs that received a subretinal injection of our XLRP product candidate.

We initially developed our gene therapy platform in clinical-stage proof-of-concept programs involving three other diseases:

Leber congenital amaurosis (type 2), or LCA2, an orphan eye disease caused by mutation in the RPE65 gene;

the wet form of age-related macular degeneration, or wet AMD, an eye disease affecting a large patient population; and

Alpha-1 antitrypsin deficiency, or AAT deficiency, an inherited orphan lung disease.

While not our principal focus at this time, these proof-of-concept programs are important because they have provided initial evidence of safety and efficacy of our gene therapy approach in both preclinical studies and clinical trials. They have also enabled us to develop substantial experience in vector design, delivery and manufacturing, clinical trial design and conduct, and in working with clinical investigators and regulatory agencies. In these proof-of-concept programs, our manufacturing process has been successfully vetted by regulatory agencies and partners and we have demonstrated our ability to produce clinical material for multiple studies.

In clinical trials conducted by our licensee Genzyme Corporation, or Genzyme, up to 34 patients with wet AMD were treated by intravitreal injection of an AAV vector, and in other trials conducted by us and others, more than 50 patients with LCA2 have been treated with subretinal injections of AAV vectors, in both cases without reports of serious adverse events attributed to the vector, and with promising indications of efficacy for LCA2 patients. See Business Strategic collaborations Our license to Genzyme. We believe our AAT deficiency program provides proof of concept for the use of our gene therapy platform in indications outside our focus area of orphan ophthalmology. We have conducted Phase 1 and Phase 2 clinical trials for our AAT deficiency product candidate in 30 patients and expect to start a Phase 2b trial in early 2015, with initial clinical data expected in mid-2015.

Table of Contents

The chart below summarizes our current gene therapy programs:

Our gene therapy platform

Our gene therapy platform is built on our core competencies in three key areas: vector selection and design, vector manufacturing and vector delivery:

Vector selection and design. The success of a gene therapy platform is highly dependent on the vector selected. Our gene therapy platform is based on viral vectors that utilize a modified version of the non-replicating adeno-associated virus to deliver a functional copy of a gene to the patient s own cells. We believe that AAV vectors are particularly well-suited for treating our target diseases and offer advantages including safety, stability and sustained expression compared with viral vectors such as adenovirus, herpes virus and lentivirus used by others. AAV vectors can carry genes of up to 4,000 base pairs in length, a carrying capacity sufficient to accommodate more than 90% of human genes.

One of our key capabilities is our understanding of the complex interplay between the clinical disease, the cells in the patient s body that need treatment, the selection of the protein shell, or capsid, and a promoter, the design of the gene construct and the physical administration method. We have spent years

Table of Contents

conducting research on the best combinations of these elements with the aim of developing safe and effective gene therapy treatments.

Vector manufacturing. We have developed a proprietary, high-yield vector manufacturing process using scalable technologies, which addresses problems of low productivity and low efficacy that have historically plagued efforts to manufacture AAV vectors and enables us to produce vectors with improved potency, efficiency and safety over processes previously used by us and others.

Our manufacturing process has been reviewed by both the FDA and the European Medicines Agency, or EMA, has been authorized for production of product candidates for use in clinical trials in the United States and Europe and has been transferred successfully to Genzyme and to our contract manufacturing organization. We hold or have licensed 79 issued and 28 pending patents covering our manufacturing technology. We believe that our core competency and intellectual property estate in vector manufacturing differentiate us competitively and provide a key element of our gene therapy platform.

Vector delivery. Our gene therapy platform allows for vector delivery by a variety of methods, and we select the method that is most beneficial for the disease we are targeting. In ophthalmology, the product candidate can best be delivered to cells in the eye by injection. For other indications, such as AAT deficiency, we plan to administer the product candidate by intramuscular injection or vascular delivery. These methods of administration are well-established for the safe and effective delivery of other drugs and protein products.

Because our AAV vectors can be used to introduce functional genes into many different cell types and by a variety of delivery methods and have a carrying capacity sufficient to accommodate most of the individual genes in the human genome, our gene therapy platform has the potential to provide treatments for many other diseases outside of our current focus on orphan ophthalmology, including those with large dosing requirements or in larger markets. We have already conducted preclinical proof-of-concept studies and Phase 1 and Phase 2 clinical trials of a treatment for AAT deficiency. We expect to explore other therapeutic areas selectively, either alone or through partnerships.

Our focus on orphan ophthalmology

We focus on orphan ophthalmology because we believe there is a significant unmet medical need in orphan eye diseases that provides an attractive business opportunity. The prevalence of the diseases we are pursuing is large by orphan standards, but small enough to permit clinical trials on a manageable scale and to provide markets that we believe can be served using a small, targeted commercial infrastructure. The eye diseases we are targeting are also of interest to us due to a number of factors that have enabled us to predict the potential safety and efficacy of our product candidates at an early stage of development:

- these diseases involve well-understood disease mechanisms;
- these are monogenic diseases, meaning they are caused by mutations in a single gene, which mitigates the uncertainty of disease biology;
- highly predictive animal models are available;
- local delivery of the therapeutic agent is possible via methods already widely used in ophthalmology;
- these diseases have clearly defined clinical endpoints that have been accepted by regulatory agencies in review of other ophthalmology products; and
- we anticipate a short time to meaningful clinical data.

Table of Contents

Our strategy

Our objective is to become the world leader in developing and commercializing gene therapy treatments for inherited orphan diseases in ophthalmology, for which there are no currently available treatments, and to thereby provide a better life for people with these diseases. Our strategy to accomplish this goal is to:

- develop and commercialize drugs in orphan ophthalmology;
- continue our leadership position in orphan ophthalmology;
- extend our expertise in AAV vector selection and design, delivery and manufacturing;
- pursue monogenic orphan indications with high unmet medical need and greater probability of clinical, regulatory and commercial success; and
- develop and partner selectively to expand the scope of our pipeline and the utilization of our gene therapy platform.

Risks associated with our business

Our ability to implement our business strategy is subject to numerous risks that you should be aware of before making an investment decision. These risks are described more fully in the section entitled Risk Factors beginning on page 12 of this prospectus. You are encouraged to read that section in its entirety before making an investment decision. These risks include, but are not limited to, the following:

- We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future.
- Our ability to generate revenue from product sales is highly uncertain and we may never achieve or sustain profitability.
- In order to obtain regulatory approval for and commercialize our product candidates we will need to raise additional funding in the future, which may not be available on acceptable terms, or at all.
- All of our product candidates are in preclinical or clinical development. Clinical drug development is expensive, time consuming and uncertain, and we may ultimately not be able to obtain regulatory approvals for the commercialization of some or all of our product candidates.
- Our gene therapy product candidates are based on a novel technology, no gene therapy products have been approved in the United States and only one such product has been approved in Europe, which makes it difficult to predict the time and cost of product candidate development and regulatory approval.
- Success in animal studies or early clinical trials may not be indicative of results obtained in later trials.

We may encounter substantial delays in our clinical trials or we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.

Even if we complete the necessary clinical trials, we cannot predict when or if we will obtain regulatory approval to commercialize a product candidate or the approval may be for a more narrow indication than we expect.

We expect to rely on third parties to conduct, supervise and monitor our clinical trials and to conduct certain aspects of our product manufacturing and protocol development, and if these third parties perform in an unsatisfactory manner, it may harm our business.

The insurance coverage and reimbursement status of our product candidates is uncertain, and failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue.

Table of Contents

Negative public opinion and increased regulatory scrutiny of gene therapy and genetic research may damage public perception of our product candidates or adversely affect our ability to conduct our business, raise additional funding, obtain regulatory approvals or achieve market acceptance for our product candidates.

If we are unable to obtain and maintain patent protection for our technology and products or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be impaired.

Corporate information

We were incorporated in Florida in January 1999 and reincorporated in Delaware in October 2003. Our principal executive offices are located at 11801 Research Drive, Suite D, Alachua, Florida 32615, and our telephone number is (386) 462-2204. Our corporate website address is www.agtc.com. Information contained on or accessible through our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is an inactive textual reference only.

We use AGTC and the double helix logo as trademarks in the United States and other countries. We have begun the registration process for these trademarks in the United States.

This prospectus contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus, including logos, artwork, and other visual displays, may appear without the ® or symbols, but such references are not intended to indicate that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other companies trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any such companies.

Implications of being an emerging growth company

As a company with less than $1 billion in revenue during our last fiscal year, we qualify as an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced Management s Discussion and Analysis of Financial Condition and Results of Operations disclosure;

reduced disclosure about our executive compensation arrangements;

no non-binding advisory votes on executive compensation or golden parachute arrangements; and

exemption from the auditor attestation requirement in the assessment of our internal controls over financial reporting.

We may take advantage of these exemptions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company if we have more than $1 billion in annual revenue, we have more than $700 million in market value of our stock held by non-affiliates or we issue more than $1 billion of non-convertible debt over a three-year period. We may choose to take advantage of some, but not all, of the available exemptions. We have taken advantage of certain reduced reporting burdens in this prospectus. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock.

Table of Contents

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Table of Contents

The Offering

Common stock offered by AGTC	4,166,667 shares
Common stock to be outstanding after this offering	13,395,787 shares (14,020,787 shares in the event the underwriters elect to exercise in full their over-allotment option to purchase additional shares from us)
Use of proceeds	We estimate that the net proceeds from this offering will be approximately $44.9 million, or approximately $51.8 million if the underwriters exercise in full their over-allotment option, based on the initial public offering price of $12.00 per share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We plan to use the net proceeds from this offering to extend development of our XLRS and ACHM product candidates beyond Phase 1/2 trials (which we believe are already adequately funded), and if successful to initiate pivotal Phase 3 trials for these product candidates, to continue preclinical studies of our XLRP product candidate and to explore in early preclinical studies potential applications of our gene therapy platform in other indications in orphan ophthalmology. We intend to use remaining amounts for working capital and other general corporate purposes. We may also use a portion of the net proceeds to in-license, acquire or invest in complementary gene therapy businesses, technologies, products or assets, as well as to selectively explore potential applications of our gene therapy platform in indications outside of orphan ophthalmology. See Use of Proceeds.
Risk factors	You should read the Risk Factors section and other information included in this prospectus for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.
Proposed NASDAQ Global Market symbol	AGTC

The number of shares of our common stock to be outstanding after this offering set forth above is based on the 109,039 shares of our common stock outstanding as of December 31, 2013 and assumes the conversion of all outstanding shares of our preferred stock into 9,120,081 shares of common stock upon the closing of this offering.

The number of shares of common stock to be outstanding after this offering excludes:

- 59,247 shares of common stock issuable upon the exercise of preferred stock warrants outstanding as of December 31, 2013, at a weighted average exercise price of $8.16 per share;
- 782,947 shares of common stock issuable upon the exercise of stock options outstanding under our 2001 Stock Option Plan and our 2011 Stock Incentive Plan as of December 31, 2013, at a weighted average exercise price of $3.23 per share;
- 250,204 shares of common stock available for future issuance under our 2001 Stock Option Plan and our 2011 Stock Incentive Plan as of December 31, 2013; and

Table of Contents

an additional 1,279,999 shares of our common stock that will be made available for future issuance under our equity compensation plans upon the closing of this offering.

Except as otherwise noted, all information in this prospectus:

gives effect to a 1-for-35 reverse split of our common stock effected on March 4, 2014;

assumes no exercise of outstanding options or warrants described above;

assumes no exercise by the underwriters of their over-allotment option to purchase 535,650 additional shares of common stock from us;

gives effect to the automatic conversion of all outstanding shares of our preferred stock into 9,120,081 shares of our common stock upon the closing of this offering; and

gives effect to the amendment and restatement of our certificate of incorporation and bylaws upon the closing of this offering.

Certain of our existing stockholders have agreed to purchase an aggregate of $6.0 million in shares of our common stock in this offering at the initial public offering price.

Table of Contents

Summary Financial Data

The following summary financial data should be read together with our financial statements and accompanying notes and Management s Discussion and Analysis of Financial Condition and Results of Operations appearing elsewhere in this prospectus. Our summary statement of operations data for the fiscal years ended June 30, 2012 and 2013 and our summary balance sheet data as of June 30, 2012 and 2013 are derived from our audited financial statements included elsewhere in this prospectus. Our summary statement of operations data for the six months ended December 31, 2012 and 2013 and our summary balance sheet data as of December 31, 2013 have been derived from our unaudited financial statements included elsewhere in this prospectus. Our historical results are not necessarily indicative of results to be expected for any future period, and our interim results are not necessarily indicative of our results for the entire year or any future period. The summary financial data in this section are not intended to replace our financial statements and the related notes.

The pro forma balance sheet data as of December 31, 2013 gives effect to the conversion of all of our preferred stock into 9,120,081 shares of common stock upon the closing of this offering and the conversion of all outstanding warrants exercisable for shares of Series A-1, Series A-1A and Series B-1 preferred stock into warrants exercisable for shares of common stock, resulting in our preferred stock warrant liability being reclassified to additional paid-in capital. The pro forma as adjusted balance sheet data as of December 31, 2013 gives effect to (1) the pro forma adjustments described above and (2) our receipt of estimated net proceeds of $44.9 million from this offering, based on the initial public offering price of $12.00 per share, after deducting underwriting discounts and estimated offering expenses payable by us, as if each had occurred as of December 31, 2013. The pro forma as adjusted summary financial data are not necessarily indicative of what our financial position would have been if this offering had been completed as of the date indicated, nor are these data necessarily indicative of our financial position for any future date or period.

	Fiscal Year Ended June 30,		Six Months Ended December 31,	
	2012	2013	2012	2013
	(in thousands except per share data)			
Statement of Operations Data:				
Revenue:				
Grant revenue	$ 718	$ 439	$ 293	$ 466
Sponsored research revenue	364	503	156	307
Total revenue	1,082	942	449	773
Operating expenses:				
Research and development	2,354	3,133	1,156	3,673
General and administrative	787	1,403	649	1,971
Total operating expenses	3,141	4,536	1,805	5,644
Loss from operations	(2,059)	(3,594)	(1,356)	(4,871)

Table of Contents

	Fiscal Year Ended June 30,		Six Months Ended December 31,	
	2012	2013	2012	2013
	(in thousands except per share data)			
Other income (expense):				
Interest income		10		15
Interest expense	(69)	(191)	(152)	
Fair value adjustments to warrant liabilities (1)	204	(8)	5	(105)
Fair value adjustments to Series B purchase rights (1)		(1,207)	(437)	(2,838)
Total other income (expense), net	135	(1,396)	(584)	(2,928)
Net loss	$ (1,924)	$ (4,990)	$ (1,940)	$ (7,799)
Net loss per share, basic and diluted (2)	$ (17.65)	$ (45.78)	$ (17.80)	$ (71.55)
Weighted-average shares outstanding, basic and diluted (2)	109	109	109	109
Pro forma net loss per share, basic and diluted (unaudited) (2)		$ (1.20)		$ (1.13)
Weighted-average pro forma shares outstanding, basic and diluted (unaudited) (2)		4,146		6,885

	As of June 30,