

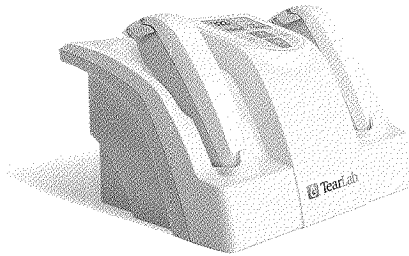


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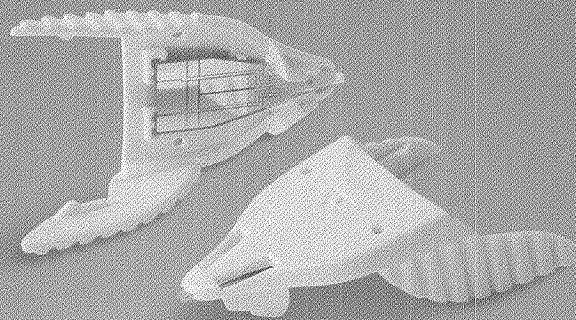
Washington, DC 20549



TEARLAB CORPORATION



2012 FORM 10-K



DIAGNOSING AND MANAGING DISEASE AT THE POINT-OF-CARE

 TearLab.

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2012

Or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_\_  
Commission file number: 000-51030

SEC  
Mail Processing  
Section

APR 29 2013

Washington DC  
59-3434781  
(I.R.S. Employer  
Identification Number)

**TearLab Corp.**

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of  
incorporation or organization)

7360 Carroll Rd., Suite 200

San Diego, California

(Address of principal executive offices)

92121  
(Zip Code)

Registrant's telephone number, including area code: (858) 455-6006

SECURITIES REGISTERED PURSUANT TO SECTION 12(B) OF THE ACT:

Title of each class  
COMMON STOCK, \$0.001 PAR VALUE

Name of each exchange on which registered  
The NASDAQ Stock Market LLC  
(The Nasdaq Capital Market)

SECURITIES REGISTERED PURSUANT TO SECTION 12(G) OF THE ACT: NONE

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 (the "Exchange Act"). Yes  No

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by a check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer

Accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company)

Smaller reporting company

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

The aggregate market value of the voting common stock held by non-affiliates of the Registrant (assuming officers, directors and 10% stockholders are affiliates), based on the last sale price for such stock on June 30, 2012: \$73,025,667. The Registrant has no non-voting common stock.

As of March 15, 2013, there were 28,765,140 shares of the Registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Proxy Statement for the 2013 Annual Meeting of Stockholders of the Registrant to be held on June 7, 2013 are incorporated by reference into Part III of this Form 10-K.

The Registrant makes available free of charge on or through its website (<http://www.tearlab.com>) its Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and any amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934. The material is made available through the Registrant's website as soon as reasonably practicable after the material is electronically filed with or furnished to the U.S. Securities and Exchange Commission, or SEC. All of the Registrant's filings may be read or copied at the SEC's Public Reference Room at 100 F Street, N.E., Room 1580, Washington D.C. 20549. Information on the hours of operation of the SEC's Public Reference Room can be obtained by calling the SEC at 1-800-SEC-0330. The SEC maintains a website (<http://www.sec.gov>) that contains reports and proxy and information statements of issuers that file electronically.

**TEARLAB CORPORATION.**

**Form 10-K – ANNUAL REPORT**

**For the Fiscal Year Ended December 31, 2012**

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## PART I

### SPECIAL NOTE REGARDING FORWARD LOOKING STATEMENTS

*This Annual Report on Form 10-K contains forward-looking statements relating to future events and our future performance within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. In some cases, you can identify forward-looking statements by terms such as "may", "will", "should", "could", "would", "hope", "expects", "plans", "intends", "anticipates", "believes", "estimates", "projects", "predicts", "potential" and similar expressions intended to identify forward-looking statements. These forward-looking statements include, without limitation, statements relating to future events, future results, and future economic conditions in general and statements about:*

- *Our future strategy, structure, and business prospects;*
- *The planned commercialization of our current product;*
- *The size and growth of the potential markets for our product and technology;*
- *The adequacy of current, and the development of new distributor, reseller, and supplier relationships, and our efforts to expand relationships with distributors and resellers in additional countries;*
- *Our anticipated expansion of United States and international sales and operations;*
- *Our ability to obtain and protect our intellectual property and proprietary rights;*
- *The results of our clinical trials;*
- *Our plan to continue to develop and execute our conference and podium strategy to ensure visibility and evidence-based positioning of the TearLab® Osmolarity System among eye care professionals;*
- *Our anticipated sales to additional customers in the United States since we obtained the CLIA waiver categorization;*
- *Our ability to obtain reimbursement for patient testing with the TearLab System;*
- *Our efforts to assist our customers in obtaining their CLIA waiver or providing them with support from certified professionals;*
- *The adequacy of our funding and our forecast of the period of time through which our financial resources will be adequate to support our operations; and*
- *Use of cash, cash needs and ability to raise capital.*

*These statements involve known and unknown risks, uncertainties and other factors, including the risks described in Part I, Item 1A. of this Annual Report on Form 10-K, which may cause our actual results, performance or achievements to be materially different from any future results, performances, time frames or achievements expressed or implied by the forward-looking statements. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements. Information regarding market and industry statistics contained in this Annual Report on Form 10-K is included based on information available to us that we believe is accurate. It is generally based on academic and other publications that are not produced for purposes of securities offerings or economic analysis. We have not reviewed or included data from all sources and cannot assure you of the accuracy of the market and industry data we have included.*

## **Corporate Information**

TearLab Corp. was incorporated as OccuLogix, Inc. in Delaware in 2002. Unless the context requires otherwise, in this report the terms "the Company," "we," "us" and "our" refer to TearLab Corp. and our subsidiaries. References to "\$" or "dollars" shall mean U.S. dollars unless otherwise indicated. References to "C\$" shall mean Canadian dollars.

### ***ITEM 1. Business.***

#### ***Overview***

We are an *in-vitro* diagnostic company based in San Diego, California. We have commercialized a proprietary tear testing platform, the TearLab® Osmolarity System that enables eye care practitioners to test for highly sensitive and specific biomarkers using nanoliters of tear film at the point-of-care. Our first product measures tear film osmolarity for the diagnosis of Dry Eye Disease, or DED. Our results are included in our financial statements, which are included under Item 8 to this Annual Report on Form 10-K.

#### **TearLab Research, Inc.**

TearLab Research, Inc. our wholly-owned subsidiary, develops technologies to enable eye care practitioners to test a wide range of biomarkers (chemistries, metabolites (i.e. glucose), genes and proteins) at the point-of-care. Commercializing that tear testing platform is now the focus of our business.

The Company's first product, the TearLab Osmolarity System, enables the rapid measurement of tear osmolarity in the doctor's office. Osmolarity is a quantitative and highly specific biomarker that has been shown to assist in the diagnosis and disease management of DED. There are estimated to be between 20 million and 40 million DED patients in the United States, and less than 5% of those patients are currently diagnosed and treated. The innovation of the TearLab Osmolarity System is its ability to precisely and rapidly measure osmolarity in nanoliter volumes of tear samples, using a highly efficient and novel tear collection system at the point of care. Historically, eye care researchers have relied on expensive instruments to perform tear biomarker analysis. In addition to their cost, these conventional systems are slow, highly variable in their measurement readings, and not categorized as waived by the United States Food and Drug Administration, or FDA, under regulations promulgated under the Clinical Laboratory Improvement Amendments, or CLIA.

The TearLab Osmolarity System consists of the following three components: (1) the TearLab disposable, which is a single-use microfluidic microchip; (2) the TearLab Pen, which is a hand-held device that interfaces with the TearLab disposable; and (3) the TearLab Reader, which is a small desktop unit that allows for the docking of the TearLab Pen and provides a quantitative reading for the operator.

In October 2008, the TearLab Osmolarity System received CE mark approval, clearing the way for sales in the European Union and all countries recognizing the CE mark. In connection with the CE mark clearance, while our current focus is on developing our business in the United States, we do have agreements with numerous distributors for distribution of the TearLab Osmolarity System in Europe and Asia.

On May 19, 2009, we announced that we received 510(k) clearance from the FDA. We submitted a CLIA waiver application for the TearLab Osmolarity System to the FDA on May 27, 2010. On March 4, 2011, we announced that we had received a communication from the FDA that the data we submitted was not sufficient to gain approval of our CLIA waiver application. On December 5, 2011, we announced that we had

received a communication from the FDA indicating that, based on a supervisory review of the Company's appeal, the FDA had granted our petition for a waiver under CLIA for the TearLab Osmolarity System. On January 23, 2012, we announced that after reviewing and accepting labeling submitted to it by the Company, the FDA had granted the waiver categorization under CLIA for the TearLab Osmolarity System. The CLIA waiver reduces the regulatory paperwork and related administrative time for customers. In the United States, we sell directly to our customers and do not utilize distributors.

On December 8, 2009 we announced that Health Canada issued a Medical Device License for the TearLab® Osmolarity System. The Health Canada license allowed us to immediately begin marketing the system in Canada. On August 20, 2009, we entered into an agreement with a distributor, Science with Vision, for exclusive distribution of the TearLab Osmolarity System in Canada. We began selling products through the Canadian distributor in 2010.

### **Current Status and Recent Financing**

On July 16, 2009, we announced that we had entered into and closed an agreement with certain investors whereby the investors agreed to provide financing, or the Financing, to the Company through the purchase of convertible secured notes, in the aggregate amount of \$1.55 million. On August 31, 2009, an additional \$200,000 of financing was received by the Company to bring the aggregate total funding received to \$1.75 million. In connection with the Financing, the Company issued warrants to purchase shares of common stock equal in value to ten percent of the aggregate principal amount of the notes. The exercise price of the warrants is \$1.60 per common share. On June 13, 2011 the outstanding liability related to the Notes was converted to common stock. The conversion price of the Notes was \$1.3186 per share. We recognized interest expense related to the Notes of \$0, \$95,000, and \$210,000 for the years ended December 31, 2012, 2011, and 2010, respectively.

On January 8, 2010, we obtained commitments for the sale of 3,244,766 shares of our common stock for an aggregate of approximately \$3,000,000 in a private placement. 1,886,291 of such shares were issued in January 2010 with the remainder being issued in March 2010, following stockholder approval for the sale of such additional shares. The price per share, sold in the private placement was \$0.92456, which is equal to 80% of the volume weighted average price of our common stock for the 10 trading days ending on the day immediately preceding the January 8, 2010 closing date.

On March 18, 2010, we sold 1,552,795 shares of our common stock and warrants to purchase an additional 621,118 shares of our common stock for gross proceeds of approximately \$5,000,000. The purchase price for the shares and warrants was \$3.22 per unit (each unit consisting of one share and a warrant to purchase 0.4 shares of common stock). The exercise price of the warrants is \$4.00 per share. The warrants were exercisable at any time during the period commencing on September 19, 2010 and ending on September 19, 2011. These warrants were not exercised and expired at the end of the period.

On June 13, 2011, the Company issued 1,629,539 shares of its common stock and warrants to purchase 109,375 shares of its common stock in consideration of conversion and retirement of the Company's outstanding July and August 2009 debt obligations in the aggregate amount of \$2,149,000, with associated issuance costs of \$41,000. The exercise price of the warrants is \$1.60 per common share representing the price per share equal to the closing bid price per share of the Company's common stock on the NASDAQ stock market on July 15, 2009. The warrants have a five year life and to date no warrants have been exercised.

On June 30, 2011, the Company sold 3,846,154 shares of its common stock and warrants to purchase approximately 3,846,154 shares of its common stock for gross proceeds of approximately \$7,000,000. The

investors purchased the shares and warrants for \$1.82 per unit (each unit consisting of one share and a warrant to purchase one share of common stock). The exercise price of the warrants is \$1.86 per share. The warrants are exercisable at any time until June 30, 2016. During 2012, 1,750,469 warrants were exercised for gross proceeds of \$3,256,000.

On April 16, 2012, the Company closed an underwritten public offering of 3.45 million shares of its common stock at a price to the public of \$3.60 per share. The Company received gross proceeds of \$12,420,000, with associated costs of \$1,194,000.

On July 18, 2012, the Company closed an underwritten registered direct financing of 2.5 million shares of its common stock at a price of \$3.17 per share. The Company received gross proceeds of \$7,925,000, with associated costs of \$524,000.

On September 17, 2012, the Company issued 316,779 shares of restricted stock units to its management team as settlement of an outstanding liability for previously accrued bonuses related to achievement of CLIA waiver status. The costs basis of the shares granted was \$3.72, the closing price of the Company's stock on the date of grant, for a total value of \$1,181,000. The shares were issued in accordance with the Company's amended 2002 Stock Incentive Plan and were fully vested on the date of grant.

## ***Industry***

### **Point-of-care Testing and Dry Eye Disease, or DED**

The global market for point-of-care testing is currently \$4.5 billion annually or 15% of the \$30 billion global market for in-vitro diagnostic products. Approximately 75% of all laboratory tests today are performed at centralized clinical laboratories. However, there is an increasing frequency of diagnostic testing being performed at the point-of-care due to several factors, including a need for rapid testing in acute care situations, the benefits of patient monitoring and disease management, streamlining therapeutic decision making and the overall trend toward personalized medicine. We believe that advances in bio-detection technologies that can simplify and accelerate the rate of performing complex diagnostic tests at the point-of-care, and that are reimbursed, will drive utilization and overall point-of-care testing market growth.

TearLab's first product is the TearLab® Osmolarity System. This test can be performed at the point-of-care for the measurement of osmolarity, a quantitative and highly specific biomarker that has shown to assist in the diagnosis and disease management of DED. There are estimated to be between 20 and 40 million people with DED in the United States alone, and this condition is estimated to account for up to one-third of all visits to U.S. eye care professionals.

Each time a person blinks, his or her eyes are resurfaced with a thin layer of a complex fluid known as the tear film. The tear film works to protect eyes from the outside world. Bacteria, viruses, sand, freezing winds and salt water (inclusive of most environmental factors) will not damage eyes when the tear film is intact. However, when compromised, a deficient tear film can be an exceedingly painful and disruptive condition. The tear film consists of three components: (i) an innermost mucin layer (produced by the surface cells); (ii) the aqueous layer (the water in tears, produced by the lacrimal gland); and (iii) an oily lipid layer which limits evaporation of the tears (produced by the meibomian glands, located at the margins of the eyelids). The apparatus of the ocular surface forms an integrated unit. When working correctly, the tear film presents a smooth optical surface essential for clear vision and proper immunity. Androgen deficiency and chronic inflammation of the lacrimal or meibomian gland may lead to the condition known as dry eye, which has been likened to arthritis of the eye, and results in a compromised, fragile tear film.



DED is often seen as a result of aging, diabetes, prostate cancer therapy, HIV, autoimmune diseases such as Sjögren's syndrome and rheumatoid arthritis, LASIK surgery, contact lens wear, menopause and as a side effect of hormone replacement therapy. Numerous commonly prescribed and over-the-counter medications also can cause, or contribute to, the manifestation of DED.

There are millions of Americans who suffer from contact lens-induced DED, and 10% to 15% of these patients revert to frame wear annually due to dryness and discomfort. There are between 500,000 and 1.5 million LASIK procedures performed in the U.S each year, and about 50% of patients experience DED post-operatively.

### **Diagnostic Alternatives for Dry Eye Disease**

Existing diagnostic assays are highly subjective, do not correlate well with symptoms, are invasive for patients and may require up to an hour of operator time to perform. All of these factors have constrained the diagnosis and treatment of the DED patient population. As physicians have not had access to objective, quantitative diagnostic assays that correlate well with symptoms and disease pathogenesis, it has been difficult for them to differentiate DED symptoms from other eye diseases that present with very similar symptoms, such as non-infectious ocular allergies or infectious bacterial or viral diseases. To treat DED effectively and to mitigate the emotional and physical effects of this disease, it will be critical to equip physicians with objective, quantitative measurements of disease pathogenesis so they can determine more accurately the most efficacious treatments for their patients.

Osmolarity in DED presents itself as an increase in the salt concentration of the tear film. For over 50 years, studies have shown that tear film osmolarity is the ideal clinical marker for diagnosing DED, providing an objective, quantitative measurement of disease pathogenesis. Measuring osmolarity also serves as an effective disease management tool by providing physicians with an ability to personalize therapeutic intervention and to track patient outcomes quantitatively. Osmolarity testing could also provide physicians with a tool to identify patients at risk for dropping out of contact lens wear early in disease progression, as well as an invaluable test to guide the type and duration of therapy prior to, and following refractive surgery.

The main challenge in measuring osmolarity at the point-of-care is the vanishingly small volume of tear available for testing. Older laboratory osmometers require upwards of ten microliters of fluid to produce a single reading. In addition, these instruments are not particularly suitable for use in a physician's office, since they require continual calibration, cleaning and maintenance. Existing osmometers currently are marketed primarily to reference and hospital laboratories for the measurement of osmolarity in blood, urine and other serum samples.

### ***TearLab's Product***

Our TearLab® Osmolarity System is an integrated testing system comprised of: (1) the TearLab disposable, which is a single-use microfluidic microchip; (2) the TearLab Pen, which is a hand-held device that interfaces with the TearLab disposable; and (3) the TearLab Reader, which is a small desktop unit that allows for the docking of the TearLab Pen and provides a quantitative reading for the operator. The innovation of the TearLab Osmolarity System is its ability to measure precisely rapidly, and inexpensively biomarkers in *nanoliter* volumes of tear samples or approximately 1,000 times less volume than required for older laboratory devices.

The operator of the TearLab Osmolarity System, most likely a technician, collects the tear sample from the patient's eye in the TearLab disposable, using the TearLab Pen. After the tear has been collected, the operator places the Pen into the Reader. The TearLab Reader then will display an osmolarity reading to the

operator. Following the completion of the test, the TearLab disposable will be discarded and a new TearLab disposable will be readied for the next test. The entire process, from sample to answer, should require approximately two minutes or less to complete.

We are currently engaged in commercial manufacturing of the TearLab® Osmolarity System. In October 2008, the TearLab Osmolarity System received CE mark approval, clearing the way for sales in the European Union and all countries recognizing the CE mark. In connection with the CE mark clearance, we have entered into multi-year agreements with numerous distributors for distribution of the TearLab Osmolarity System. In December 2009, Health Canada issued a Medical Device License for the TearLab Osmolarity System allowing us to market our product in Canada.

In May 2009, we received 510(k) approval from the FDA to aid in the diagnosis of patients with signs and symptoms of DED. The 510(k) enables us to sell our product to customers that have moderate or high complexity CLIA certificates in the United States. In addition, we have been awarded ISO 13485 certification for our quality management system. ISO 13485 is an internationally-accepted standard of quality management for medical device manufacturers.

On March 4, 2011, the Company announced that it was in receipt of a communication from the FDA indicating that the data submitted by the Company was not sufficient to gain approval of its CLIA waiver categorization application for the TearLab® Osmolarity System. The Company appealed to the FDA and on December 5, 2011, we announced that we had received a communication from the FDA indicating that, based on a supervisory review of the Company's appeal, the FDA had granted our petition for a waiver under CLIA for the TearLab Osmolarity System. On January 23, 2012, we announced that after reviewing and accepting labeling submitted to it by the Company, the FDA had granted the Waiver categorization under CLIA for the TearLab Osmolarity System.

While our current focus is on building our business in the United States, we do have distributorship agreements in place in Europe and Asia.

## **Competition**

To date, we have identified one laboratory technology that claims to be able to measure the osmolarity of nanoliter tear samples, the LacriPen. This device is listed as "under development" by Lacrisciences, LLC (Washington, DC, US). This device does not have FDA 510(k) clearance nor a CLIA waiver, and is not at the commercial stage at this time. One other non-osmolarity based in vitro diagnostic test for dry eye has recently been developed by RPS, Inc., of Sarasota Florida. RPS has commercialized a tear test for dry eye that measures MMP-9 in Canada. This test is not yet FDA cleared and does not have a CLIA waiver. In addition, ATD (Advanced Tear Diagnostics) has a CLIA classification of Moderately Complex in the United States. This system measures lactoferrin and IgE in human tears.

As there are no commercially available instruments to measure tear film osmolarity at the point-of-care, TearLab views existing DED diagnostic tests, such as the Schirmer Test and ocular surface staining, as its primary source of competition.

Tear film break-up time, or TBUT, is another assay meant as an indication of tear film stability. However, it is subjective, requires a physician to instill a carefully controlled amount of fluorescein dye into the eye and requires a stopwatch to determine the endpoint. TBUT has been shown to be unreliable as a determinant of DED since shortened TBUT does not always correlate well with other signs or symptoms.

Tests like impression cytology and corneal staining, although indicative of relatively late stage phenomena in DED, are subjective, qualitative and generally do not correlate to disease pathogenesis. The Schirmer Test is an imprecise marker of tear function since its diagnostic results vary significantly.

Although, at the present time, there does not appear to be a direct competitor to the TearLab® Osmolarity System, many industry participants have much greater resources than us. This means that those industry participants may be able to make greater investments in research and development, marketing, promotion and sales, than we are capable of right now or will be capable of during the foreseeable future.

### **Principal Suppliers**

We rely on a single supplier, Sparton Medical Systems located in the United States, for the manufacture of the Readers and Pens which are key components of the TearLab® Osmolarity System. We also rely on a single supplier, MiniFAB (Aust) Pty Ltd. located in Australia, for the manufacture of the test cards which is also a key component of the TearLab Osmolarity System.

### ***Patents and Proprietary Rights***

We own or have exclusive licenses to multiple patents and applications relating to the TearLab Osmolarity System and related technology and processes:

- eight issued U.S. patents; relating to the TearLab Osmolarity System and related technology and processes and have applied for a number of other patents in the United States and other jurisdictions;
- three pending U.S. patent applications;
- eighteen pending patent applications in countries/regions other than the United States, including six applications in Europe, four applications in Japan, three applications in Canada, two in Australia, one application in Brazil and two applications in Mexico; and
- one granted Australian patent, one granted Chinese patent and one granted Mexican patent.

We intend to rely on know-how, continuing technological innovation and in-licensing opportunities to further develop our proprietary position. Our ability to obtain intellectual property protection for the TearLab® Osmolarity System and related technology and processes, and our ability to operate without infringing the intellectual property rights of others and to prevent others from infringing our intellectual property rights, will have a substantial impact on our ability to succeed in our business. Although we intend to seek to protect our proprietary position by, among other methods, continuing to file patent applications, the patent position of companies like TearLab is generally uncertain and involves complex legal and factual questions. Our ability to maintain and solidify a proprietary position for our technology will depend on our success in obtaining effective claims and enforcing those claims once granted. We do not know whether any part of our patent applications will result in the issuance of any patents. Our issued patents, those that may be issued in the future or those licensed to us, may be challenged, invalidated or circumvented, which could limit our ability to stop would-be competitors from marketing tests identical to the TearLab Osmolarity System.

In addition to patent protection, we have registered the TearLab trademark in the United States, the European Union, Japan, Korea, Mexico, the Russian Federation and Turkey. Our TearLab trademark applications are pending in Canada and China.

## ***Government Regulation***

Government authorities in the United States and other countries extensively regulate, among other things, the research, development, testing, manufacture, labeling, promotion, advertising, distribution and marketing of our product, which is a medical device. In the United States, the FDA regulates medical devices under the Federal Food, Drug, and Cosmetic Act and implementing regulations. Failure to comply with the applicable FDA requirements, both before and after approval, may subject us to administrative and judicial sanctions, such as a delay in approving or refusal by the FDA to approve pending applications, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, administrative fines or criminal prosecution.

Unless exempted by regulation, medical devices may not be commercially distributed in the United States unless they have been cleared or approved by the FDA. Medical devices are classified into one of the three classes, Class I, II or III, on the basis of the controls necessary to reasonably assure their safety and effectiveness. Class I devices are subject to general controls, such as labeling, pre-market notification and adherence to good manufacturing practices. The TearLab® Osmolarity System is a Class I, non-exempt device and qualifies for the 510(k) procedure. Under the FDA's Section 510(k) procedure, the manufacturer provides a pre-market notification that it intends to begin marketing the product, and shows that the product is substantially equivalent to another legally marketed product, that it has the same intended use and is as safe and effective as a legally marketed device and does not raise different questions of safety and effectiveness than does a legally marketed device. In some cases, the submission must include data from human clinical studies. Marketing may commence when the FDA issues a clearance letter finding substantial equivalence. On May 19, 2009, we announced that we received FDA 510(k) clearance of the TearLab Osmolarity System.

After a device receives 510(k) clearance, any modification to the device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, would require a new 510(k) clearance or an approval of a Premarket Approval, or PMA. A PMA is the FDA process of scientific or regulatory review to evaluate the safety and effectiveness of Class III medical devices which are those devices which support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. Although the FDA requires the manufacturer to make the initial determination regarding the effect of a modification to the device that is subject to 510(k) clearance, the FDA can review the manufacturer's determination at any time and require the manufacturer to seek another 510(k) clearance or an approval of a PMA.

CLIA is intended to ensure the quality and reliability of clinical laboratories in the United States by mandating specific standards in the areas of personnel qualifications, administration, participation in proficiency testing, patient test management, quality control, quality assurance and inspections. The regulations promulgated under CLIA establish three levels of *in vitro* diagnostic tests: (1) waiver; (2) moderately complex; and (3) highly complex. The standards applicable to a clinical laboratory depend on the level of diagnostic tests it performs. A CLIA waiver is available to clinical laboratory test systems if they meet certain requirements established by the statute. Waived tests are simple laboratory examinations and procedures employing methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible or to pose no reasonable risk of harm to patients if the examinations or procedures are performed incorrectly. These tests are waived from regulatory oversight of the user other than the requirement to follow the manufacturer's labeling and directions for use.

On March 4, 2011, the Company announced that it was in receipt of a communication from the FDA indicating that the data submitted by the Company was not sufficient to gain approval of its CLIA waiver categorization application for the TearLab® Osmolarity System. The Company appealed to the FDA and on December 5, 2011, we announced that we had received a communication from the FDA indicating that, based

on a supervisory review of the Company's appeal, the FDA had granted our petition for a waiver under CLIA for the TearLab Osmolarity System. On January 23, 2012, we announced that after reviewing and accepting labeling submitted to it by the Company, the FDA had granted the waiver categorization under CLIA for the TearLab Osmolarity System.

Regardless of whether a medical device requires FDA clearance or approval, a number of other FDA requirements apply to the device, its manufacturer and those who distribute it. Device manufacturers must be registered and their products listed with the FDA, and certain adverse events and product malfunctions must be reported to the FDA. The FDA also regulates the product labeling, promotion and, in some cases, advertising, of medical devices. In addition, manufacturers and their suppliers must comply with the FDA's quality system regulation which establishes extensive requirements for quality and manufacturing procedures. Thus, suppliers, manufacturers and distributors must continue to spend time, money and effort to maintain compliance, and failure to comply can lead to enforcement action. The FDA periodically inspects facilities to ascertain compliance with these and other requirements.

### ***Research and Development Expenditure***

Our research and development expense was \$2.2 million, \$1.3 million and \$1.4 million in the years ended December 31, 2012, 2011 and 2010, respectively.

### ***Employees***

On December 31, 2012, we had 48 full-time employees.

### ***Available Information***

Our corporate Internet address is [www.tearlab.com](http://www.tearlab.com). At the Investor Relations section of this website, we make available free of charge our Annual Report on Form 10-K, our Annual Proxy statement, our quarterly reports on Form 10-Q, any Current Reports on Form 8-K, and any amendments to these reports, as soon as reasonably practicable after we electronically file them with, or furnish them to, the U.S. Securities and Exchange Commission, or the SEC. The information found on our website is not part of this Annual Report on Form 10-K. In addition to our website, the SEC maintains an Internet site at [www.sec.gov](http://www.sec.gov) that contains reports, proxy and information statements, and other information regarding us and other issuers that file electronically with the SEC.

## **ITEM 1A. RISK FACTORS**

*This Annual Report contains forward-looking statements that involve risks and uncertainties that could cause our actual results to differ materially from those discussed in this Annual Report. These risks and uncertainties include the following:*

### **Risks Relating to our Business**

***Our near-term success is highly dependent on the success of the TearLab® Osmolarity System, and we cannot be certain that it will be successfully commercialized in the United States.***

The TearLab Osmolarity System is currently our only product. Our product is currently sold outside of the United States pursuant to CE mark approval; in Canada pursuant to a Health Canada Medical Device License; and in the United States as a result of having received 510(k) approval from the U.S. Food and Drug Administration, or the FDA, to market the TearLab Osmolarity System to those reference and physician operated laboratories with Clinical Laboratory Improvement Act, or CLIA, waiver certifications. Even though the TearLab Osmolarity System has received all regulatory approvals in the United States, it may never be successfully commercialized. If the TearLab Osmolarity System is not as successfully commercialized as expected, we may not be able to generate revenue, become profitable or continue our operations. Any failure of the TearLab Osmolarity System to be successfully commercialized in the United States would have a material adverse effect on our business, operating results, financial condition and cash flows and could result in a substantial decline in the price of our common stock.

***Our near-term success is highly dependent on increasing sales of the TearLab Osmolarity System outside the United States, and we cannot be certain that we will successfully increase such sales.***

Our product is currently sold outside of the United States pursuant to CE mark approval and Health Canada Approval in Canada. Our near-term success is highly dependent on increasing our international sales. We may also be required to register our product with health departments in our foreign market countries. A failure to successfully register in such markets would negatively affect our sales in any such markets. In addition, import taxes are levied on our product in certain foreign markets. These foreign markets include Turkey, Spain, Italy and France. Other countries may adopt taxation codes on imported products. Increases in such taxes or other restrictions on our product could negatively affect our ability to import, distribute and price our product.

***Our commitment to purchase minimum levels of product from our suppliers may result in the purchase of excess quantities of product if we are not able to successfully commercialize the TearLab Osmolarity System.***

On August 1, 2011, we entered into a manufacturing and development agreement, or the Manufacturing Agreement, with MiniFAB (Aust) Pty Ltd, or MiniFAB. Pursuant to the terms of the Manufacturing Agreement, MiniFAB will manufacture and supply test cards for us. The Manufacturing Agreement specifies minimum order quantities that will require us to purchase approximately USD \$26.1 million (AUD\$25.1 million) in test cards from MiniFAB for the years 2013 through the end of 2015. Each year, we must purchase the covered test cards exclusively from MiniFAB until the minimum order quantity for such year has been met. The Manufacturing Agreement has a ten-year initial term and may be terminated by either party if the other party is in breach or becomes insolvent. If terminated for any reason other than a default by MiniFAB, we will be obligated to pay a termination fee based on the cost of products manufactured by MiniFAB, but not yet invoiced, repayment of capital invested by MiniFAB, less

depreciation calculated in accordance with Australian accounting standards, and the expected profit to MiniFAB had the remaining minimum order quantities been purchased by us.

The usage of test cards purchased under the minimum purchase commitment with MiniFAB is predicated upon significant increases in revenue from the TearLab products as compared to the year ended December 31, 2012 and prior periods. If we are not able to commercialize the TearLab® Osmolarity System sufficiently to sell the minimum order quantities required by the MiniFab Agreement, we will be required to purchase test cards that we may be unable to use and that may become obsolete, which would have a potentially adverse effect on our financial position, results of operations and cash flows.

***Our limited working capital and history of losses have resulted in doubts as to whether we will be able to continue as a going concern.***

In the years ended December 31, 2012 and 2011, we have prepared our consolidated financial statements on the basis that we would continue as a going concern. However, we have incurred losses in each year since our inception. Our net working capital balance at December 31, 2012 was \$9.3 million, which represents a \$10.1 million increase in the balance from our working capital deficit of \$0.8 million at December 31, 2011. During the year ended December 31, 2012, the Company raised gross proceeds of \$3.4 million from the exercise of warrants and stock options, \$12.4 million in an underwritten public offering and \$7.9 million in a registered direct financing.

Although current levels of cash flows are negative, management believes the Company's existing cash will be sufficient to cover its operating and other cash demands for at least the next 12 months.

Our consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary if we were not able to continue as a going concern.

***We have incurred losses since inception and anticipate that we will incur continued losses for the foreseeable future.***

We have incurred losses in each year since our inception. As of December 31, 2012, we had an accumulated deficit of \$406.8 million. Our losses have resulted primarily from expenses incurred in research and development of our product candidates from the former retina and glaucoma business divisions. We do not know when or if we will successfully commercialize the TearLab Osmolarity System in the United States. As a result, and because of the numerous risks and uncertainties facing us, it is difficult to provide the extent of any future losses or the time required to achieve profitability, if at all. Any failure of our product to become and remain profitable would adversely affect the price of our common stock and our ability to raise capital and continue operations.

***We have outstanding liabilities, which could adversely affect our ability to adjust our business to respond to competitive pressures and to obtain sufficient funds to satisfy our future research and development needs, and to defend our intellectual property.***

As of December 31, 2012, our total liabilities were approximately \$9.3 million. Our significant liability service requirements could adversely affect our ability to operate our business and may limit our ability to take advantage of potential business opportunities. For example, our high level of liability presents the following risks:

- our liabilities increase our vulnerability to economic downturns and adverse competitive and industry conditions and could place us at a competitive disadvantage compared to those of our competitors that are less leveraged;
- our liability obligations could limit our flexibility in planning for, or reacting to, changes in our business and our industry and could limit our ability to pursue other business opportunities, borrow money for operations or capital in the future and implement our business strategies; and
- our level of liabilities may restrict us from raising additional funds on satisfactory terms to fund working capital, capital expenditures, product development efforts, strategic acquisitions, investments and alliances, and other general corporate requirements.

If we are at any time unable to generate sufficient cash flow to service our liabilities when payment is due, we may be required to attempt to renegotiate the terms of the instruments relating to the liabilities, seek to refinance all or a portion of the liabilities or obtain financing. There can be no assurance that we will be able to successfully renegotiate such terms, that any such refinancing would be possible or that any additional financing could be obtained on terms that are favorable or acceptable to us.

***We may not be able to raise the capital necessary to fund our operations.***

Since inception, we have funded our operations through debt and equity financings, including the 2009 convertible secured debt financings, the 2010 private placement and registered direct common stock financings and the 2011 private placement financings, the exercise of warrants in March 2012 by warrant holders, the April 2012 public offering financing as well as the July 2012 registered direct financing. As of the date of filing of this quarterly Form 10-K, we estimate that our cash and cash equivalents will be sufficient to meet our operating activities and other demands for at least the next 12 months. However, our prospects for obtaining additional financing are uncertain. Additional capital may not be available on terms favorable to us, or at all. If financing is available, it may not be sufficient for us to continue as a going concern and it may be on terms that adversely affect the interest of our existing stockholders. In addition, future financings could result in significant dilution of existing stockholders and adversely affect the economic interests of existing stockholders.

***We will face challenges in bringing the TearLab® Osmolarity System to market in the United States and may not succeed in executing our business plan.***

There are numerous risks and uncertainties inherent in the development of new medical technologies. In addition to our requirement for additional capital, our ability to bring the TearLab Osmolarity System to market in the United States and to execute our business plan successfully is subject to the following risks, among others:

- Our clinical trials may not succeed. Clinical testing is expensive and can take longer than originally anticipated. The outcomes of clinical trials are uncertain, and failure can occur at any stage of the testing. We could encounter unexpected problems, which could result in a delay in efforts to complete clinical trials supporting our commercialization efforts.
- The TearLab Osmolarity System is rated under a CLIA waiver certification which requires our customers to be certified under the CLIA waiver requirements to be reimbursed under Medicare, including certain parallel state requirements. If our customers are unwilling or unable to comply with such requirements, it could have an adverse effect on their acceptance of and on our ability to market the TearLab Osmolarity System in the United States.
- Our suppliers and we will be subject to numerous FDA requirements covering the design, testing, manufacturing, quality control, labeling, advertising, promotion and export of the TearLab Osmolarity System and other matters. If our suppliers or we fail to comply with these regulatory



requirements, the TearLab Osmolarity System could be subject to restrictions or withdrawals from the market and we could become subject to penalties.

- Even though we were successful in obtaining the sought-after FDA approvals, we may be unable to commercialize the TearLab Osmolarity System successfully in the United States. Successful commercialization will depend on a number of factors, including, among other things, achieving widespread acceptance of the TearLab Osmolarity System among physicians, establishing adequate sales and marketing capabilities, addressing competition effectively, the ability to obtain and enforce patents to protect proprietary rights from use by would-be competitors, key personnel retention and ensuring sufficient manufacturing capacity and inventory to support commercialization plans.

***If we are subject to regulatory enforcement action as a result of our failure to comply with regulatory requirements, our commercial operations would be harmed.***

While we received the 510(k) clearance and CLIA waiver that we were seeking, we will be subject to significant ongoing regulatory requirements, and if we fail to comply with these requirements, we could be subject to enforcement action by the FDA or state agencies, including:

- adverse publicity, warning letters, fines, injunctions, consent decrees and civil penalties;
- repair, replacement, refunds, recall or seizure of our product;
- operating restrictions or partial suspension or total shutdown of production;
  - delay or refusal of our requests for 510(k) clearance or premarket approval of new products or of new intended uses or modifications to our existing product;
- withdrawing 510(k) clearances or premarket approvals that have already been granted; and
- criminal prosecution.

If any of these enforcement actions were to be taken by the government, our business could be harmed.

We are required to demonstrate and maintain compliance with the FDA's Quality System Regulation, or the QSR. The QSR is a complex regulatory scheme that covers the methods and documentation of the design, testing, control, manufacturing, labeling, quality assurance, packaging, storage and shipping of our products. The FDA must determine that the facilities which manufacture and assemble our products that are intended for sale in the United States, as well as the manufacturing controls and specifications for these products, are compliant with applicable regulatory requirements, including the QSR. The FDA enforces the QSR through periodic unannounced inspections. Our facilities have not yet been inspected by the FDA, and we cannot assure you that we will pass any future FDA inspection. Our failure, or the failure of our suppliers, to take satisfactory corrective action in response to an adverse QSR inspection could result in enforcement actions, including a public warning letter, a shutdown of our manufacturing operations, a recall of our product, civil or criminal penalties or other sanctions, which would significantly harm our available inventory and sales and cause our business to suffer.

***Our patents may not be valid, and we may not be able to obtain and enforce patents to protect our proprietary rights from use by would-be competitors. Patents of other companies could require us to stop using or pay to use required technology.***

Our owned and licensed patents may not be valid, and we may not be able to obtain and enforce patents and to maintain trade secret protection for our technology. The extent to which we are unable to do so could materially harm our business.

We have applied for, and intend to continue to apply for, patents relating to the TearLab® Osmolarity System and related technology and processes. Such applications may not result in the issuance of any patents, and any patents now held or that may be issued may not provide adequate protection from competition. Furthermore, it is possible that patents issued or licensed to us may be challenged successfully. In that event, if we have a preferred competitive position because of any such patents, any preferred position would be lost. If we are unable to secure or to continue to maintain a preferred position, the TearLab Osmolarity System could become subject to competition from the sale of generic products.

Patents issued or licensed to us may be infringed by the products or processes of others. The cost of enforcing patent rights against infringers, if such enforcement is required, could be significant and the time demands could interfere with our normal operations. There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical, biotechnology and medical technology industries. We could become a party to patent litigation and other proceedings. The cost to us of any patent litigation, even if resolved in our favor, could be substantial. Some of our would-be competitors may be able to sustain the costs of such litigation more effectively than we can because of their substantially greater financial resources. Litigation may also absorb significant management time.

Unpatented trade secrets, improvements, confidential know-how and continuing technological innovation are important to our future scientific and commercial success. Although we attempt to, and will continue to attempt to, protect our proprietary information through reliance on trade secret laws and the use of confidentiality agreements with corporate partners, collaborators, employees and consultants and other appropriate means, these measures may not effectively prevent disclosure of our proprietary information, and, in any event, others may develop independently, or obtain access to, the same or similar information.

Certain of our patent rights are licensed to us by third parties. If we fail to comply with the terms of these license agreements, our rights to those patents may be terminated, and we will be unable to conduct our business.

It is possible that a court may find us to be infringing upon validly issued patents of third parties. In that event, in addition to the cost of defending the underlying suit for infringement, we may have to pay license fees and/or damages and may be enjoined from conducting certain activities. Obtaining licenses under third-party patents can be costly, and such licenses may not be available at all.

***We may face future product liability claims.***

The testing, manufacturing, marketing and sale of therapeutic and diagnostic products entail significant inherent risks of allegations of product liability. Our past use of the RHEO™ System and the components of the SOLX Glaucoma System in clinical trials and the commercial sale of those products may have exposed us to potential liability claims. Our use of the TearLab® Osmolarity System and its commercial sale could also expose us to liability claims. All of such claims might be made directly by patients, health care providers or others selling the products. We carry clinical trials and product liability insurance to cover certain claims that could arise, or that could have arisen, during our clinical trials or during the commercial use of our products. We currently maintain clinical trials and product liability insurance with coverage limits of \$2,000,000 in the aggregate annually. Such coverage, and any coverage obtained in the future, may be inadequate to protect us in the event of successful product liability claims, and we may not be able to increase the amount of such insurance coverage or even renew it. A successful product liability claim could materially harm our business. In addition, substantial, complex or extended litigation could result in the incurrence of large expenditures and the diversion of significant resources.

***We have entered into a number of related party transactions with suppliers, creditors, stockholders, officers and other parties, each of which may have interests which conflict with those of our public stockholders.***

We have entered into several related party transactions with our suppliers, creditors, stockholders, officers and other parties, each of which may have interests which conflict with those of our public stockholders.

***If we do not introduce new commercially successful products in a timely manner, our products may become obsolete over time, customers may not buy our products and our revenue and profitability may decline.***

Demand for our products may change in ways we may not anticipate because of:

- evolving customer needs;
- the introduction of new products and technologies; and
- evolving industry standards.

Without the timely introduction of new commercially successful products and enhancements, our products may become obsolete over time, in which case our sales and operating results would suffer. The success of our new product offerings will depend on several factors, including our ability to:

- properly identify and anticipate customer needs;
- commercialize new products in a cost-effective and timely manner;
- manufacture and deliver products in sufficient volumes on time;
- obtain and maintain regulatory approval for such new products;
- differentiate our offerings from competitors' offerings;
- achieve positive clinical outcomes; and
- provide adequate medical and/or consumer education relating to new products.

Moreover, innovations generally will require a substantial investment in research and development before we can determine the commercial viability of these innovations and we may not have the financial resources necessary to fund these innovations. In addition, even if we are able to successfully develop enhancements or new generations of our products, these enhancements or new generations of products may not produce revenue in excess of the costs of development and they may be quickly rendered obsolete by changing customer preferences or the introduction by our competitors of products embodying new technologies or features.

***We rely on a single supplier of each of the key components of the TearLab® Osmolarity System and are vulnerable to fluctuations in the availability and price of our suppliers' products and services.***

We purchase each of the key components of the TearLab® Osmolarity System from single third-party suppliers. Our supplier may not provide the components or other products needed by us in the quantities requested, in a timely manner or at a price we are willing to pay. In the event we were unable to renew our agreements with our supplier or they were to become unable or unwilling to continue to provide important components in the required volumes and quality levels or in a timely manner, or if regulations affecting the components were to change, we would be required to identify and obtain acceptable replacement supply sources. We may not be able to obtain alternative suppliers or vendors on a timely basis, or at all, which could disrupt or delay, or halt altogether, our ability to manufacture or deliver the TearLab Osmolarity

System. If any of these events should occur, our business, financial condition, cash flows and results of operations could be materially adversely affected.

***We face intense competition, and our failure to compete effectively could have a material adverse effect on our results of operations.***

We face intense competition in the markets for ophthalmic products and these markets are subject to rapid and significant technological change. Although we have no direct competitors, we have numerous potential competitors in the United States and abroad. We face potential competition from industry participants marketing conventional technologies for the measurement of osmolarity and other in-lab testing technologies, and commercially available methods, such as the Schirmer Test and ocular surface staining. Many of our potential competitors have substantially more resources and a greater marketing scale than we do. If we are unable to develop and produce or market our products to effectively compete against our competitors, our operating results will materially suffer.

***If we lose key personnel, or we are unable to attract and retain highly qualified personnel on a cost-effective basis, it would be more difficult for us to manage our existing business operations and to identify and pursue new growth opportunities.***

Our success depends, in large part, upon our ability to attract and retain highly qualified scientific, clinical, manufacturing and management personnel. In addition, any difficulties retaining key personnel or managing this growth could disrupt our operations. Future growth will require us to continue to implement and improve our managerial, operational and financial systems, and to continue to recruit, train and retain additional qualified personnel, which may impose a strain on our administrative and operational infrastructure. The competition for qualified personnel in the medical technology field is intense. We are highly dependent on our continued ability to attract, motivate and retain highly qualified management, clinical and scientific personnel.

Due to our limited resources, we may not be able to effectively recruit, train and retain additional qualified personnel. If we are unable to retain key personnel or manage our growth effectively, we may not be able to implement our business plan.

Furthermore, we have not entered into non-competition agreements with our key employees. In addition, we do not maintain "key person" life insurance on any of our officers, employees or consultants. The loss of the services of existing personnel, the failure to recruit additional key scientific, technical and managerial personnel in a timely manner, and the loss of our employees to our competitors would harm our research and development programs and our business.

***If we fail to establish and maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired, which would adversely affect our consolidated operating results, our ability to operate our business and our stock price.***

Ensuring that we have adequate internal financial and accounting controls and procedures in place to produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be re-evaluated frequently. Failure on our part to maintain effective internal financial and accounting controls would cause our financial reporting to be unreliable, could have a material adverse effect on our business, operating results, financial condition and cash flows, and could cause the trading price of our common stock to fall dramatically.

Maintaining proper and effective internal controls will require substantial management time and attention and may result in our incurring substantial incremental expenses, including with respect to increasing the breadth and depth of our finance organization to ensure that we have personnel with the appropriate qualifications and training in certain key accounting roles and adherence to certain control disciplines within the accounting and reporting function. Any failure in internal controls or any errors or delays in our financial reporting would have a material adverse effect on our business and results of operations and could have a substantial adverse impact on the trading price of our common stock.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP. Our management does not expect that our internal control over financial reporting will prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Our management has identified control deficiencies in the past and may identify additional deficiencies in the future.

We cannot be certain that the actions we are taking to improve our internal controls over financial reporting will be sufficient or that any changes processes and procedures can be completed in a timely manner. In future periods, if the process required by Section 404 of the Sarbanes-Oxley Act of 2002 reveals material weaknesses or significant deficiencies, the correction of any such material weaknesses or significant deficiencies could require additional remedial measures which could be costly and time-consuming. In addition, we may be unable to produce accurate financial statements on a timely basis. Any of the foregoing could cause investors to lose confidence in the reliability of our consolidated financial statements, which could cause the market price of our common stock to decline and make it more difficult for us to finance our operations and growth.

***The trading price of our common stock may be volatile.***

The market prices for, and the trading volumes of, securities of medical device companies, such as ours, have been historically volatile. The market has experienced, from time to time, significant price and volume fluctuations unrelated to the operating performance of particular companies. The market price of our common shares may fluctuate significantly due to a variety of factors, including:

- the results of pre-clinical testing and clinical trials by us, our collaborators and/or our competitors;
- technological innovations or new diagnostic products;
- governmental regulations;
- developments in patent or other proprietary rights;
- litigation;
- public concern regarding the safety of products developed by us or others;
- comments by securities analysts;
- the issuance of additional shares to obtain financing or for acquisitions;
- general market conditions in our industry or in the economy as a whole; and
- political instability, natural disasters, war and/or events of terrorism.

In addition, the stock market has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of individual companies. Broad market and industry factors may seriously affect the market price of companies' stock, including ours, regardless of actual operating performance. In the past, following periods of volatility in the overall market and the market price

of a particular company's securities, securities class action litigation has often been instituted against these companies. This litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources.

***Because we do not expect to pay dividends on our common stock, stockholders will benefit from an investment in our common stock only if it appreciates in value.***

We have never paid cash dividends on our common stock and have no present intention to pay any dividends in the future. We are not profitable and may not earn sufficient revenues to meet all operating cash needs for at least several years, if at all. As a result, we intend to use all available cash and liquid assets in the development of our business. Any future determination about the payment of dividends will be made at the discretion of our board of directors and will depend upon our earnings, if any, our capital requirements, our operating and financial conditions and on such other factors as our board of directors may deem relevant. As a result, the success of an investment in our common stock will depend upon any future appreciation in its value. There is no guarantee that our common stock will appreciate in value or even maintain the price at which stockholders have purchased their shares.

***Warrant holders will not be entitled to any of the rights of common stockholders, but will be subject to all changes made with respect thereto.***

If you hold warrants, you will not be entitled to any rights with respect to our common stock (including, without limitation, voting rights and rights to receive any dividends or other distributions on our common stock), but you will be subject to all changes affecting our common stock. You will have rights with respect to our common stock only if you receive our common stock upon exercise of the warrants and only as of the date when you become a record owner of the shares of our common stock upon such exercise. For example, if an amendment is proposed to our charter or bylaws requiring stockholder approval and the record date for determining the stockholders of record entitled to vote on the amendment occurs prior to the date you are deemed to be the owner of the shares of our common stock due upon exercise of your warrants, you will not be entitled to vote on the amendment, although you will nevertheless be subject to any changes in the powers, preferences or special rights of our common stock.

***We can issue shares of preferred stock that may adversely affect the rights of holders of our common stock.***

Our certificate of incorporation authorizes us to issue up to 10,000,000 shares of preferred stock with designations, rights, and preferences determined from time to time by our board of directors. Accordingly, our board of directors is empowered, without stockholder approval, to issue preferred stock with dividend, liquidation, conversion, voting or other rights superior to those of holders of our common stock. For example, an issuance of shares of preferred stock could:

- adversely affect the voting power of the holders of our common stock;
- make it more difficult for a third party to gain control of us;
- discourage bids for our common stock at a premium;
- limit or eliminate any payments that the holders of our common stock could expect to receive upon our liquidation; or
- otherwise adversely affect the market price of our common stock.

**ITEM 2. Properties.**

Our world-wide headquarters, occupying approximately 6,500 square feet and used for administrative, sales, marketing, research and development, and finance activities, is located in San Diego, California. The current arrangement ends on June 30, 2015, but the Company has exercised its option to terminate the lease at the end of June 2013. The total future minimum obligation under this lease is \$62,000 for 2013.

We believe that the San Diego, California facility is not suitable and adequate to support our current operations and will take advantage of the option to terminate our current lease at the end of June 2013. We have signed a new lease arrangement for a facility located in San Diego, California occupying approximately 13,800 usable square footage that will end on June 30, 2018. The total future minimum obligation under this lease is \$1,387,000 for the five year term with the 2013 obligation being \$74,000.

**ITEM 3. Legal Proceedings.**

We are not aware of any material litigation involving us that is outstanding, threatened or pending.

**ITEM 4. Mine Safety Disclosures.**

Not applicable.

## PART II

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

#### **Market for Common Equity**

Our common stock trades on the NASDAQ Capital Market ("NASDAQ") under the symbol "TEAR" and the Toronto Stock Exchange ("TSX") under the symbol "TLB".

The following table sets forth the range of high and low sales prices per share of our common stock on both the NASDAQ and the TSX for the fiscal periods indicated.

	Common Stock Prices			
	Fiscal 2012		Fiscal 2011	
	High	Low	High	Low
NASDAQ Capital Market				
First Quarter .....	\$ 3.89	\$ 1.07	\$ 2.90	\$ 1.34
Second Quarter.....	\$ 4.88	\$ 2.75	\$ 2.20	\$ 1.62
Third Quarter.....	\$ 4.10	\$ 3.07	\$ 2.05	\$ 0.88
Fourth Quarter.....	\$ 4.78	\$ 3.65	\$ 2.25	\$ 0.78
TSX				
First Quarter .....	C\$ 3.85	C\$ 1.10	C\$ 2.97	C\$ 1.45
Second Quarter.....	\$ 4.62	\$ 2.84	\$ 2.12	\$ 1.48
Third Quarter.....	\$ 3.98	\$ 3.10	\$ 2.00	\$ 0.95
Fourth Quarter.....	\$ 4.70	\$ 3.77	\$ 2.26	\$ 0.75

The closing share price for our common stock on March 15, 2013 as reported by NASDAQ, was \$6.10. The closing share price for our common stock on March 15, 2013, as reported by TSX, was C\$6.16.

As of March 15, 2013, there were approximately 92 stockholders of record of our common stock.

#### **Dividend Policy**

We have never declared or paid any cash dividends on shares of our capital stock. We currently intend to retain all available funds to support operations and to finance the growth and development of our business. Any determination related to payments of future dividends will be at the discretion of our board of directors after taking into account various factors that our board of directors deems relevant, including our financial condition, operating results, current and anticipated cash needs, plans for expansion and debt restrictions, if any.

#### **Sales of Unregistered Securities**

None.

#### **Stock Performance Graph**

The following graph compares the cumulative total stockholder return data for our common stock to the cumulative return of (i) the NASDAQ Composite Index and (ii) the NASDAQ Medical Equipment Index for the period beginning December 9, 2004, and ending on December 31, 2012. The graph assumes that \$100



was invested on January 1, 2007, and assumes reinvestment of dividends. The stock price performance on the following graph is not necessarily indicative of future stock price performance.

This performance graph shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or incorporated by reference into any filing of TearLab Corp. under the Securities Act, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

**ITEM 6. Selected Financial Data.**

The following selected financial data should be read in conjunction with our consolidated financial statements, the related notes thereto and the information contained in "Item 7 – Management's Discussion and Analysis of Financial Condition and Results of Operations".

	Year Ended December 31,				
	2008	2009	2010	2011	2012
	(in thousands, except per share data)				
<b>Consolidated Statements of Operations Data:</b>					
Revenue.....	\$ 458	\$ 869	\$ 1,701	\$ 2,124	3,960
Cost of goods sold.....	<u>163</u>	<u>568</u>	<u>849</u>	<u>1,626</u>	<u>2,295</u>
Gross profit.....	295	301	852	498	1,665
Operating expenses					
Amortization of intangible assets .....	1,207	1,215	1,215	1,215	1,215
General and administrative.....	4,233	3,245	3,753	3,842	4,770
Clinical, regulatory and research and development.....	2,965	1,121	1,365	1,304	2,241
Sales and marketing .....	820	646	1,463	2,195	5,471
Restructuring charges .....	<u>2,441</u>	<u>—</u>	<u>—</u>	<u>—</u>	<u>—</u>
Total operating expenses .....	11,666	6,227	7,796	8,556	13,697
Other income (expense)	<u>1,665</u>	<u>(362)</u>	<u>261</u>	<u>(751)</u>	<u>(7,280)</u>
Loss from continuing operations					
before income taxes.....	(9,706)	(6,288)	(6,683)	(8,809)	(19,312)
Recovery of income taxes.....	<u>338</u>	<u>1,903</u>	<u>—</u>	<u>—</u>	<u>—</u>
Net loss .....	<u>\$ (9,368)</u>	<u>\$ (4,385)</u>	<u>\$ (6,683)</u>	<u>\$ (8,809)</u>	<u>\$ (19,312)</u>
<b>Per Share Data:</b>					
Net loss per share — basic and diluted.....	<u>\$ (2.29)</u>	<u>\$ (0.44)</u>	<u>\$ (0.47)</u>	<u>\$ (0.50)</u>	<u>\$ (0.76)</u>
Weighted average number of shares used in per share calculations —					
basic and diluted.....	4,084	9,855	14,098	17,745	25,490

	As of December 31,				
	2008	2009	2010	2011	2012
	(in thousands)				
<b>Consolidated Balance Sheet Data:</b>					
Cash and cash equivalents .....	\$ 2,565	\$ 106	\$ 2,726	\$ 2,807	\$ 15,437
Working capital (deficiency) .....	1,550	(2,132)	420	(767)	9,341
Total assets .....	13,405	9,733	11,535	10,538	24,139
Convertible notes payable and accrued interest (including current portion due to stockholders) .....	23	1,281	1,697	28	—
Total .....	3,446	2,976	3,658	5,018	9,295
Contingently redeemable stock .....	250	—	—	—	—
Common stock .....	10	10	15	20	29
Additional paid-in capital .....	377,356	378,790	386,588	393,035	421,662
Accumulated deficit .....	(367,657)	(372,043)	(378,726)	(387,535)	(406,847)
Total stockholders' equity .....	9,709	6,757	7,877	5,520	14,844

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

*The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes, included in Item 8 of this Report. Unless otherwise specified, all dollar amounts are U.S. dollars.*

**Overview**

We are an *in vitro* diagnostic company that has developed a proprietary tear testing platform, the TearLab® Osmolarity System. The TearLab test measures tear film osmolarity for diagnosis of Dry Eye Disease, or DED. Tear osmolarity is a quantitative and highly specific biomarker that has been shown to correlate with DED. The TearLab test enables the rapid measurement of tear osmolarity in a doctor's office. Commercializing our Point-of-Care tear testing platform is now the focus of our business.

In October 2008, the TearLab Osmolarity System received CE mark approval, clearing the way for sales in the European Union and all countries recognizing the CE mark. In connection with the CE mark clearance, we have entered into multi-year agreements with numerous distributors for distribution of the TearLab Osmolarity System. Currently, we have signed distribution agreements in each of the following countries: Spain, Portugal, Germany, France, Turkey, Ukraine, Bulgaria, Belgium, Netherlands, Switzerland, Finland, Sweden, Denmark, Norway, South Korea, Australia, Russia, Hungary, Greece, Canada, Slovakia, Argentina, the Czech Republic, a sales representation agreement in Japan and are selling directly to the customer in the United Kingdom.

On May 19, 2009, we announced that we received 510(k) clearance from the U.S. Food and Drug Administration, or FDA. The 510(k) clearance allows us to market the TearLab Osmolarity System to those reference and physician operated laboratories with CLIA certifications allowing them to perform moderate and high complexity tests. Considering that most of our target customers currently are eye care practitioners without such certifications, it was necessary that we obtained a CLIA waiver from the FDA for the TearLab

Osmolarity System as well as assisting our customers in obtaining their moderate complexity CLIA certification or providing them with support from certified professionals. A CLIA waiver greatly reduces the regulatory compliance for our customers.

On March 4, 2011, we announced that we received communication from the FDA indicating that the data submitted by the Company was not sufficient to gain approval of the CLIA waiver categorization application for the TearLab® Osmolarity System. We appealed to the FDA and on December 5, 2011, we announced that we had received a communication from the FDA indicating that, based on a supervisory review of the Company's appeal, the FDA had granted our petition for a waiver under CLIA for the TearLab Osmolarity System. On January 23, 2012, we announced that after reviewing and accepting labeling submitted to it by the Company, the FDA had granted the waiver categorization under CLIA for the TearLab Osmolarity System.

On December 8, 2009 we announced that Health Canada issued a Medical Device License for the TearLab Osmolarity System. The Health Canada license allowed us to immediately begin marketing the system in Canada. On August 20, 2009, we entered into an agreement with a distributor, Science with Vision, for exclusive distribution of the TearLab Osmolarity System in Canada. We began selling products through the Canadian distributor in 2010.

On October 19, 2010 we announced that a unique new Current Procedural Terminology, or CPT, code that will apply to the TearLab Osmolarity test had been published by the American Medical Association, or AMA. The new code became effective January 1, 2011. The new CPT code for the TearLab Osmolarity test is: *83861; Microfluidic analysis utilizing an integrated collection and analysis device, tear osmolarity (For microfluidic tear osmolarity of both eyes, report 83861 twice)*. This code falls under the Chemistry sub-section of the Pathology and Laboratory section of the CPT Codebook and was listed under the 2010 Clinical Laboratory Fee Schedule by the Centers for Medicare and Medicaid Services, or CMS. Reimbursement by CMS was set at \$24.01 per eye and was only available for offices that had a Moderate Complex CLIA certificate. Under the 2011 Clinical Laboratory Fee Schedule listed by CMS the reimbursement rate was reduced to \$23.58 and was applicable to a majority of states in the U.S. On December 13, 2011, we announced that CMS published instructions for updates to the clinical laboratory fee schedule for 2012, including a revised reimbursement rate for the TearLab® Osmolarity Test, effective January 1, 2012. The payment code of 83861 that currently applies to the TearLab Osmolarity Test will be cross-walked or paired with code 84081. At current 2012 reimbursement rates, payment code 83861 would be reimbursed in every state by CMS at \$23.40 per eye. This decision by CMS provides level reimbursement for and equal access to the TearLab Osmolarity Test across all states which was not the case in 2011.

Our success is highly dependent on our ability to increase sales of our testing platform in Europe and other countries recognizing the CE mark, in Canada where we have a Medical Device License and with our receipt of the CLIA waiver early in 2012 which will enable us to begin full commercialization efforts in the United States. Meeting these objectives requires that we have sufficient capital to fund our operations. While our cash of \$15.4 million as of December 31, 2012 may be insufficient to fund our planned operations and our ability to generate increased revenues is uncertain, management believes that we have sufficient cash to fund our operations at current levels for at least the next 12 months. In spite of having adequate funding at this time we continue to evaluate various financing possibilities. If our revenues do not increase sufficiently to meet operational needs, we would be required to raise additional capital to fund our operations.

## RESULTS OF OPERATIONS

### Revenues, Cost of Goods Sold and Gross Margin

	For the years ended December 31, (in thousands)				
	2012	Change	2011	Change	2010
Revenue .....	\$ 3,960	86%	\$ 2,124	25%	\$ 1,701
Cost of goods sold .....	\$ 2,295	42%	\$ 1,626	92%	\$ 849
Gross margin .....	\$ 1,665	234%	\$ 498	(42)%	\$ 852
Percentage of total revenues .....	42%		23%		50%

#### Revenues

TearLab revenue consists of sales of the TearLab Osmolarity System, which is a hand-held tear film test for the measurement of tear osmolarity, a quantitative and highly specific biomarker that has shown to correlate with DED.

The TearLab Osmolarity System consists of the following three components: (1) the TearLab disposable, which is a single-use microfluidic labcard; (2) the TearLab pen, which is a hand-held device that interfaces with the TearLab disposable; and (3) the TearLab reader, which is a small desktop unit that allows for the docking of the TearLab disposable and the TearLab pen and provides a quantitative reading for the operator.

Having received 510(k) approval from the FDA in the United States, we have begun selling to customers in the United States who hold CLIA moderate and high complexity certificates and actively supported and assisted our customers to obtain their moderate complexity CLIA certificates or provided them with support from certified professionals. Having obtained a CLIA waiver certificate in early 2012, we will continue to actively support our customers in obtaining their CLIA waiver documentation which will allow us to sell our product to the approximately 50,000 eye care practitioners in the United States that are candidates to operate under a CLIA waiver certification.

We are working with our established distributors in Europe and Asia to increase sales. The ability for re-imbursement to be obtained in many of those countries where we have distributors will facilitate our ability to increase sales and stimulate the commercialization process. In countries where we have distributors, we are supporting physicians in local clinical trials and providing them with the required guidance to understand the relationship between DED and osmolarity and how to manage their patients with objective diagnostic data. In the United Kingdom, we are selling directly to the customer and will monitor the success of this approach to determine whether to expand direct selling on other European and Asian countries.

Having received a medical device license from Health Canada in December 2009, we have been selling the TearLab® Osmolarity Systems into Canada via a distributor in 2010, 2011 and 2012 and have established a co-operative marketing agreement with AMO Canada to market our product and support the sale of AMO drugs related to DED in Canada.

We believe that it is important that eye care professionals in the United States develop a clinical understanding of the TearLab Osmolarity System. In December 2009, we put in place a program to facilitate this education process in which we provide customers with test cards to allow them to perform initial studies to determine the prevalence of dry eye disease in their practices. As a result of this program, clinical trial costs will increase to reflect the free cards being provided for clinical trial purposes.

During the years ended December 31, 2012, 2011 and 2010, the Company recognized revenue from the sale of TearLab equipment and test cards of \$3,960,000, \$2,124,000 and \$1,701,000, respectively.

### *Cost of Goods Sold*

TearLab cost of sales includes costs of goods sold, warranty, and royalty costs. Our cost of goods sold consists primarily of costs for the manufacture of the TearLab test, including the costs we incur for the purchase of component parts from our suppliers, applicable freight and shipping costs, fees related to warehousing and logistics inventory management. Also included in TearLab costs of goods sold for the year ended December 31, 2011 was the inventory reserve provision for excess inventory of \$490,000, while in the year ended December 31, 2012 the inventory reserve provision was not material. There were no inventory reserve costs or recoveries in the year ended December 31, 2010.

### *Gross Margin*

During fiscal 2012 as compared with fiscal 2011, our combined gross margin percentage increased from 23% to 42% primarily due to the recording of a \$490,000 excess inventory reserve in the year ended December 31, 2011, offset by higher level of North American sales volume. In the year ended December 31, 2012, there was a recovery of excess inventory reserves of \$4,000 and increased North American sales volume primarily due to three year commitment contracts where upfront costs reduce initial margins on these contracts.

During fiscal 2011 as compared with fiscal 2010, our combined gross margin decreased from 50% to 23% primarily due to a recording of a \$490,000 excess inventory reserve in the year ended December 31, 2011 offset by a higher level of North American sales volume over 2010. The year ended December 31, 2010 did not include inventory reserve costs or recoveries.

### *Operating Expenses*

	For the years ended December 31, (in thousands)				
	2012	Change	2011	Change	2010
Amortization of intangible assets .....	\$ 1,215	0%	\$ 1,215	0%	\$ 1,215
General and administrative .....	4,770	24%	3,842	2%	3,753
Clinical, regulatory and research and development .....	2,241	72%	1,304	(4)%	1,365
Sales and marketing .....	5,471	149%	2,195	50%	1,463
Total operating expenses .....	<u>\$ 13,697</u>	60%	<u>\$ 8,556</u>	10%	<u>\$ 7,796</u>

### *Amortization of Intangible Assets*

Amortization expense of intangible assets remained unchanged for the years ended December 31, 2012, 2011, and 2010, as there were no adjustments to the Company's cost basis or estimated useful life of the underlying assets.

### *General and Administrative Expenses*

General and administrative expenses increased by \$928,000 or 24% during the year ended December 31, 2012, as compared with fiscal 2011. Employee salary expense increased by \$641,000 (including a non-cash CLIA bonus accrual increase of \$445,000 related to the increased market value of

TearLab's shares), non-cash stock option costs increased by 188,000, fees related to corporate activities increased by \$65,000, administrative costs increased by \$21,000.

General and administrative expenses increased by \$89,000 or 2% during the year ended December 31, 2011, as compared with fiscal 2010. Employee salary expense increased by \$695,000 (including a CLIA bonus accrual of \$238,000), professional fees related to various corporate activities increased by \$186,000 and were offset by non-cash stock option expense which decreased by \$711,000 in the current year.

We are continuing to focus our efforts on controlling costs by reviewing and improving upon our existing business processes and cost structure.

#### *Clinical, Regulatory and Research and Development*

Clinical, regulatory and research and development expenses increased by \$937,000 or 72% during the year ended December 31, 2012, as compared with fiscal 2011. Non-cash stock options expense increased by \$281,000, employee related costs increased by \$381,000 (including a non-cash CLIA bonus accrual increase of \$346,000 related to the increased market value of TearLab's shares), increased product development costs of \$376,000, increased clinical trial costs in 2012 of \$48,000, offset by lower professional fees of \$162,000 regarding regulatory and clinical activities .

Clinical, regulatory and research and development expenses decreased by \$61,000 or 4% during the year ended December 31, 2011, as compared with fiscal 2010. Non-cash stock options expense related to consultants decreased by \$77,000, along with a one-time credit for clinical trials of \$50,000. Employee related compensation and bonus costs increased by \$33,000 (including a CLIA bonus accrual of \$162,000).

#### *Sales and Marketing Expenses*

Sales and marketing expenses increased by \$3,276,000 or 149% during the year ended December 31, 2012, as compared with fiscal 2011, non-cash stock options expenses increased by \$481,000, employee related costs increased by \$1,391,000 (including a non-cash CLIA bonus accrual increase of \$296,000 related to the increased market value of TearLab's shares) primarily due to the transition from a contracted sales force to an internal TearLab sales team , associated increased internal travel costs of \$322,000, increased advertising and marketing costs of \$1,027,000 and increased administrative costs of \$52,000 consistent with increased commercialization efforts in the United States.

Sales and marketing expenses increased by \$732,000 or 50% during the year ended December 31, 2011, as compared with fiscal 2010 driven by the Company's commercialization efforts in the United States. The increase is due to \$283,000 in sales and business development costs associated with the commercialization of the TearLab product in the United States that were not present in the prior year. Additionally there was a net \$310,000 increase in marketing advertising and travel expense, reflecting additional marketing production and trade show activity over the prior year period. Also there was an accrual of \$150,000 related to the CLIA bonus.

The cornerstone of our sales and marketing strategy to date has been to increase awareness of our products among eye care professionals and, in particular, the key opinion leaders in the eye care professions. We assist key opinion leaders in performing clinical trials to generate increased data to provide an increased understanding in the use of the TearLab® Osmolarity System for diagnostic, treatment and monitoring of patients. Presently we are expanding our commercialization efforts in North America, Europe, and Asia. We

will continue to develop and execute our conference and podium strategy to ensure visibility and evidence-based positioning of the TearLab® Osmolarity System among eye care professionals.

***Other Income (Expense), Net***

	For the years ended December 31, (in thousands)				
	2012	Change	2011	Change	2010
Interest income .....	\$ 30	400%	\$ 6	71%	\$ 21
Changes in fair value of warrant obligation.....	(7,296)	(7862)%	94	(87)%	701
Warrant issue costs .....	—	100%	(303)	(100)%	—
Interest expense .....	—	100%	(95)	55%	(210)
Amortization of financing costs and beneficial conversion features .....	—	100%	(402)	(76)%	(228)
Other expense .....	(14)	73%	(51)	(122)%	(23)
	<u>\$ (7,280)</u>	<u>(869)%</u>	<u>\$ (751)</u>	<u>(388)%</u>	<u>\$ 261</u>

***Interest Income***

Interest income consists of interest income earned on our cash and cash equivalents. The fluctuations in interest income during years ended December 31, 2012, 2011 and 2010, are due to fluctuations in the Company's average cash and variations in average interest rates.

***Changes in Fair Value of Warrant Obligation***

For the year ended December 31, 2012 the Company recorded an expense of \$7,296,000 related to changes in the fair value of warrant obligations, while recording income of \$94,000 and \$701,000 for the years ended December 31, 2011 and 2010, respectively.

At January 1, 2012, the Company had a total of 4,087,026 warrants subject to fair value re-measurement each quarter. During the first quarter of 2012 certain holders of warrants exercised 1,373,700 warrants. The Company is required to record the outstanding warrants at fair value at the time of exercise, resulting in an adjustment to the warrant obligations, with any gain or loss recorded in earnings of the applicable reporting period. The Company, therefore, estimated the fair value of the exercised warrants during the first quarter 2012 to be \$2,849,000, an increase of \$1,792,000 from the previous value at December 31, 2011. This increase was recorded as a charge to other income (expense) in the consolidated statement of operations for the three months ended March 31, 2012. During the second quarter of 2012 certain holders of warrants exercised 376,769 warrants. The Company estimated the fair value of the exercised warrants during the second quarter 2012 to be \$1,166,000, an increase of \$148,000 from the previous value at March 31, 2012. This increase was recorded as a charge to other income (expense) in the consolidated statement of operations for the three months ended June 30, 2012.

In addition, the Company is also required to record the outstanding warrants at fair value at the end of each reporting period, resulting in an adjustment to the warrant obligations, with any gain or loss recorded in earnings of the applicable reporting period. The Company, therefore, estimated the fair value of the remaining warrants as of December 31, 2012 to be \$6,239,000, an increase of \$3,282,000 from the previous value at December 31, 2011. These amounts were recorded as a charge to other income (expense) in the consolidated statement of operations for the year ended December 31, 2012, the primary driver of this change being a change in Black-Scholes valuation inputs for our increased stock price.

A decrease of \$94,000 and \$701,000 at December 31, 2011 and 2010, respectively, in the fair value of warrant obligations are recorded as a gain in other income for the years ended December 31, 2011 and 2010, respectively.

#### *Interest Expense*

In the third quarter of 2009, the Company closed an agreement with certain investors whereby the investors agreed to provide financing, or the Financing, to the Company through the purchase of convertible secured notes, in the aggregate amount of \$1.75 million. The convertible secured notes, or the Notes, evidencing the Financing, were to mature on the second anniversary of their issuance, bearing interest at a rate of 12% per annum and were convertible into shares of the Company's common stock upon the request of holders of 51% or more of the outstanding principal amount of the Notes at any time after August 31, 2009 and prior to maturity. On June 13, 2011, the Notes were converted to common stock, with interest expense of \$0, \$95,000, and \$210,000 recorded for the years ended December 31, 2012, 2011, and 2010, respectively.

#### *Amortization of Finance Costs*

As a result of the financing that the Company completed in July and August 2009, or the Financing, and which resulted in the purchase of \$1.75 million in convertible secured notes by the investors, or the Notes, investors were in a position to convert the Notes at a conversion price of \$1.3186 per share at a time when the common shares of the Company were trading at \$1.75 (July 15th) and \$1.70 (August 31st) providing them with a beneficial conversion feature. The Company valued this feature as \$728,000 and the amortization of this amount was expensed over the term of the Notes until conversion in June 2011. As such, amortization expense for the years ended December 31, 2012, 2011, and 2010 was \$0, \$314,000 and \$177,000, respectively.

Investors in the Financing received 109,375 warrants at an exercise price of \$1.60 upon conversion of the Notes. The Company valued these warrants using the Black-Scholes value model at a value of \$163,000. The amortization of this amount was recorded over the term of the Notes until they were converted in June 2011 and amounted to \$0, \$69,000 and \$41,000 for the years ended December 31, 2012, 2011 and 2010, respectively.

Issuance costs of the Financing totaled \$87,000 and have been allocated to cost of equity and to deferred finance charges. The amortization of deferred finance charges was recorded over the term of the Notes until they were converted in June 2011 and amounted to \$0, \$19,000 and \$10,000 for the years ended December 31, 2012, 2011, and 2010, respectively.

#### *Other Income (Expense)*

Other expense for the year ended December 31, 2012 consists primarily of foreign exchange loss of \$15,000 due to exchange rate fluctuations on our foreign currency transactions.

Other expense for the year ended December 31, 2011 consists primarily of foreign exchange loss of \$29,000 due to exchange rate fluctuations on our foreign currency transactions, along with a one-time adjustment of \$20,000 related to an assessment by a Canadian government entity.

Other expense for the year ended December 31, 2010 consists primarily of foreign exchange loss of \$34,000 due to exchange rate fluctuations on our foreign currency transactions, offset by a gain totaling \$7,000 for the disposal of fixed assets.



## ***Liquidity and Capital Resources***

	As of December 31, (\$ in thousands)	
	2012	2011
Cash and cash equivalents .....	\$ 15,437	\$ 2,807
Percentage of total assets .....	64%	27%
Working capital (deficiency) .....	\$ 9,341	\$ (767)

### ***Financial Condition***

Management believes that we have sufficient cash to fund our operations at current levels for at least the next 12 months.

Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties. Actual results could vary as a result of a number of factors. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Our future funding requirements will depend on many factors, including but not limited to:

- whether government and third-party payers agree to reimburse the TearLab® Osmolarity System;
- whether eye care professionals engage in the process of obtaining their CLIA waiver certification;
- the costs and timing of building the infrastructure to market and sell the TearLab Osmolarity System;
- the cost and results of continuing development of TearLab Corp.'s TearLab Osmolarity System;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and
- the effect of competing technological and market developments.
- Our purchases of test cards are in Australian dollars and fluctuations in the exchange rate between the US dollar and Australian dollar may be material. In 2012, exchange rate incurred to purchase Australian dollar to pay our Australian supplier fluctuated from \$0.98 USD to \$1.08 USD per \$1.00 AUD.

At the present time, our only product is the TearLab Osmolarity System, and although we have received 510(k) approval from the FDA and a CLIA waiver approval from the FDA, at this time, we do not know when we can expect to begin to generate significant revenues from the TearLab Osmolarity System in the United States.

We believe that we have sufficient funding to meet operational needs until the Company becomes cash flow positive from operations but if we are not able to achieve a cash positive operating position in the future we may need to raise additional funds, and our prospects for obtaining that capital are uncertain. Additional capital may not be available on terms favorable to us, or at all. In addition, future financings could result in significant dilution of existing stockholders.

### ***Ongoing Sources and Uses of Cash***

We anticipate that our cash and cash equivalents and cash generated from increased revenues, will be sufficient to sustain our operations for at least the next 12 months. We continually evaluate various financing possibilities but we typically expect our primary sources of cash will be related to the collection of accounts

receivable and, to a lesser degree, interest income on our cash balances. Our accounts receivable collections will be impacted by our ability to grow our point-of-care revenue.

We expect our primary uses of cash will be to fund our operating expenses and pursuing and maintaining our patents and trademarks. In addition, dependent on available funds, we expect to expend cash to improve production capability of the TearLab test, to further improve the performance of the TearLab test, and to pursue additional applications for the lab-on-a-chip technology.

### ***Changes in Cash Flows***

	Years ended December 31, (in thousands)				
	2012	Change	2011	Change	2010
Cash used in operating activities .....	\$ (8,800)	\$ (2,826)	\$ (5,974)	\$ (1,434)	\$ (4,540)
Cash used in investing activities .....	(569)	(413)	(156)	(101)	(55)
Cash provided by financing activities....	<u>21,999</u>	<u>15,788</u>	<u>6,211</u>	<u>(1,004)</u>	<u>7,215</u>
Net increase in cash and cash equivalents during the year .....	<u>\$ 12,630</u>	<u>\$ 12,549</u>	<u>\$ 81</u>	<u>\$ (2,539)</u>	<u>\$ 2,620</u>

### ***Cash Used in Operating Activities***

Net cash used to fund our operating activities during the year ended December 31, 2012 was \$8,800,000 which is lower than our net loss of \$19,312,000 primarily due to non-cash charges. The non-cash charges which comprise a portion of the net loss during that period consist primarily of the amortization of intangible assets, fixed assets, patents and trademarks, non-cash bonuses paid in common shares and stock-based compensation expense in the aggregate total of \$11,298,000.

Net cash used to fund our operating activities during the year ended December 31, 2011 was \$5,974,000 which is lower than our net loss of \$8,809,000 primarily due to non-cash charges. The non-cash charges which comprise a portion of the net loss during that period consist primarily of the amortization of intangible assets, fixed assets, patents and trademarks, accrued interest on the convertible debt funding, amortization of deferred financing charges, warrants & beneficial conversion values, advisory fees paid in common shares and stock-based compensation expense in the aggregate total of \$2,625,000 offset partially by income arising from the revaluation of obligation under warrants of \$94,000. The net loss was increased by cash costs of \$303,000 for issue costs of warrants in the June 2011 private placement financing.

The net change in non-cash working capital and non-current asset balances related to operations for the years ended December 31, 2012, 2011 and 2010 consists of the following (*in thousands*):

	2012	2011	2010
Accounts receivable.....	(557)	(5)	(163)
Due from related parties .....	(11)	126	(130)
Inventory.....	(965)	(343)	(359)
Prepaid expenses .....	(197)	132	16
Other current assets .....	(25)	(20)	17
Other non-current assets .....	(27)	—	100
Accounts payable.....	849	(135)	(95)
Accrued liabilities.....	146	374	347
Deferred revenue .....	—	(128)	(23)
Due to stockholders .....	—	—	(10)
	<u>\$ (787)</u>	<u>\$ 1</u>	<u>\$ (300)</u>

Explanations of the more significant net changes in working capital and non-current asset balances are as follows:

- Accounts receivable increased in 2012, 2011 and 2010 as a result of increased revenues in 2012, 2011 and 2010 related to sales of the TearLab® Osmolarity System.
- Inventory increased in each of 2012, 2011 and 2010 primarily due to the increase in inventory purchases to support the projected ramp up in commercialization of the TearLab products.
- Prepaid expenses increased in 2012 from 2011 and decreased in 2011 from 2010 primarily due to the timing of annual payments made, termination of prepaid advisory agreements and reduced prepaid insurance costs.
- Non-current assets increased in 2012 from \$0 in 2011 reflecting a security deposit on premises to be leased in 2013 which will be outstanding for greater than 12 months.
- Accounts payable movement year over year is primarily due to the timing of payment cycles and the increase in commercial activities.
- Accrued liabilities have increased in each of 2012 and 2011 as a result of the CLIA bonus accrued as a result of the TearLab achieving CLIA waiver status for the TearLab® Osmolarity System resulting in a significant increase in operational activity offset by the payment of advisory agreement fees in 2011 and increased in 2010 primarily as a result of increased accruals for amounts due to employees and increased levels of operations in line with increased commercialization efforts.
- Decrease in deferred revenue in 2011, and 2010 arose from the amortization of licensing fees and from the shipment of product previously paid for.

#### *Cash used in Investing Activities*

Net cash used in investing activities for the years ended December 31, 2012, 2011 and 2010 was \$569,000, \$156,000 and \$55,000, respectively, used to acquire fixed assets, net of disposals.

#### *Cash Provided by Financing Activities*

Net cash provided by financing activities for the year ended December 31, 2012 was \$21,999,000 and is primarily made up of \$12,420,000 raised during 2012 from the issuance common stock in a public offering, \$7,925,000 raised during 2012 in a registered direct offering both offset by costs incurred in these transactions of \$1,718,000, as well as \$3,262,000 raised as a result of warrant exercises and \$110,000 raised as a result of option exercises.

Net cash provided by financing activities for the year ended December 31, 2011 was \$6,211,000 and is made up primarily of \$7,000,000 raised during 2011 from the issuance of common stock in a PIPE transaction, offset by \$789,000 in financing fees and fees for services related to the PIPE transaction.

Net cash provided by financing activities for the year ended December 31, 2010 was \$7,215,000 and is made up primarily of \$3,000,000 raised during 2010 from the issuance of common stock in a PIPE transaction and the \$5,000,000 raised from the issuance of common stock in a registered direct fundraising, offset by \$807,000 in financing fees and fees for services related to the PIPE and registered direct transactions. In addition, there was \$22,000 in funds related to the exercise of options.

#### *Borrowings*

As of December 31, 2010, we had a balance of \$1,669,000 in convertible notes payable and accrued interest arising from an agreement with investors in July and August of 2009, (as described in Note 8 in the

Notes to the financial statements). The convertible notes payable and accrued interest were converted into common shares in the second quarter of 2011. There are no other outstanding long-term debt or balances available under credit agreements.

### *Contractual Obligations and Contingencies*

The following table (*in thousands*) summarizes our contractual commitments as of December 31, 2012 and the effect those commitments are expected to have on liquidity and cash flow in future periods.

	<b>Payments Due by Period</b>			
	<b>Total</b>	<b>Less than 1 year</b>	<b>1 to 3 years</b>	<b>More than 3 years</b>
Purchase commitments .....	\$ 26,070	\$ 5,678	\$ 20,392	\$ —
Operating leases.....	1,480	144	536	800
Royalty payments .....	1,050	70	140	840
Total.....	<u>\$ 28,600</u>	<u>\$ 5,892</u>	<u>\$ 21,068</u>	<u>\$ 1,640</u>

Purchase commitment obligations represent our contractually obligated minimum purchase requirements as outlined in a manufacturing and development agreement for test cards for the Company. The agreement is denominated in AUD and as such actual amounts paid in USD may differ.

### *Off-Balance-Sheet Arrangements*

As of December 31, 2012, we did not have any material off-balance-sheet arrangements as defined in Item 303(a)(4)(ii) of SEC Regulation S-K.

### *Critical Accounting Policies and Estimates*

Our discussion and analysis of our financial condition and results of operations is based upon our audited consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amount of assets, liabilities, sales and expenses, and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates, including those related to our intangible assets, uncollectible receivables, inventories, debt and equity instruments and stock-based compensation. We base our estimates on historical experience and on various other assumptions that we believe to be 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. Because this can vary in each situation, actual results may differ from these estimates under different assumptions or conditions.

We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our audited consolidated financial statements.

### **Revenue Recognition**

We recognize revenue when all four of the following criteria are met: (i) persuasive evidence that an arrangement exists; (ii) delivery of the products has occurred; (iii) the selling price is fixed or determinable; and (iv) collectability is reasonably assured. Amounts received in excess of revenue recognizable are deferred.

Subsequent to its launch in the fourth quarter of 2008, the Company's revenues have been derived from sales of the TearLab® Osmolarity System for DED which consists of hardware and related disposables. The Company's sales are currently to countries in North America, Europe, and Asia, and are generally transacted through distributors outside of the United States. The Company records revenue when all of its obligations are completed which is generally upon shipment of the Company's products.

In 2012, the majority of our revenues are derived from the sale of disposable test cards and we expect this trend to continue for the foreseeable future. We loan our proprietary TearLab Systems at no cost to our customers, who are primarily eye care professionals, who in turn purchase the disposable test cards for use in osmolarity testing procedures. In addition, we place our proprietary systems with our customers for an extended period at no up-front cost to them. Our disposable test cards are currently shipped from our primary distribution and warehousing operations facility located in Frederick, Colorado. We generally recognize revenue for disposables test cards when the test cards are shipped to the customers.

The Company enters into contracts where revenue is derived from multiple deliverables containing a mix of products, which generally includes either the sale or the right to use a TearLab Osmolarity System and sales of a fixed number of test cards. The Company either sells readers and test cards as a combined unit with no future commitments on behalf of the client or allows the customer to use the readers with a commitment to fulfill a minimum purchase obligation, typically over a three year period. Revenue recognition for contracts with multiple deliverables is based on the individual units of accounting determined to exist in the contract. A delivered item is considered a separate unit of accounting when the delivered item has value to the customer on a stand-alone basis. Items are considered to have stand-alone value when they are sold separately by any vendor or when the customer could resell the item on a stand-alone basis. Considering that test cards are essential to the operation of a TearLab reader, there is no alternative vendor for the test cards and no indication that a secondary market for the TearLab readers is established, the deliverables under the contracts entered into during 2012 and 20122 do not meet criteria for separation under the multiple-element arrangements guidance. Consideration is allocated at the inception of the contract to all deliverables based on their relative selling price. The relative selling price for each deliverable is determined using vendor specific objective evidence (VSOE) of selling price or third-party evidence of selling price if VSOE does not exist. If neither VSOE nor third-party evidence exists, the Company uses its best estimate of the selling price for the deliverable. The Company recognizes revenue for each of the elements only when it determines that all applicable recognition criteria have been met.

#### **Accounts receivable and allowance for doubtful accounts**

The Company's accounts receivable consist primarily of trade receivables from customers and are generally unsecured and due within 30 days. The Company evaluates the collectability of its accounts receivable based on a combination of factors. Expected credit losses related to trade receivables are recorded as an allowance for doubtful accounts in the Consolidated Balance Sheets as of December 31, 2012 and 2011. The allowance for doubtful accounts is charged to sales and marketing expense and accounts receivable are written off as uncollectible and deducted from the allowance after appropriate collection efforts have been exhausted. The carrying value of accounts receivable approximates their fair value due to their short term nature. To date, charges for bad debt expense have not been material.

#### **Inventory Valuation and reserves**

Inventory is recorded at the lower of cost (based on first in, first out basis) or market and consists of finished goods. Inventory is periodically reviewed for evidence of slow-moving or obsolete items, and the estimated reserve is based on management's reviews of inventories on hand, compared to estimated future usage and sales, reviewing product shelf-life, and assumptions about the likelihood of obsolescence. The

Company has entered into a long term purchase commitment to buy the test cards from MiniFAB. The purchase commitment contains required minimum annual purchases. As part of our consideration of excess or obsolete inventory, the Company considers future annual minimum purchases, estimated future usage and the expiry dating of the cards in its analysis of any inventory reserve needed. The usage of the minimum purchase commitment is predicated upon significant increases in revenues from TearLab products as compared to 2012 and prior years.

As of December 31, 2012, 2011 and 2010, we had inventory reserves of \$0, \$601,000 and \$116,000, respectively. During the years ended December 31, 2012, 2011 and 2010, we recognized a provision for excess and obsolete inventory of \$62,000, \$490,000 and \$0, respectively, and recovery of \$66,000, \$5,000 and \$8,000, respectively. At December 31, 2012, we estimated that we would fully utilize the minimum commitment of cards and that a provision for future loss was not required.

### **Valuation of Intangible and other Long-lived Assets.**

We periodically assess the carrying value of intangible and other long-lived assets, which requires us to make assumptions and judgments regarding the future cash flows of these assets. The assets are considered to be impaired if we determine that the carrying value may not be recoverable based upon our assessment of the following events or changes in circumstances:

- the asset's ability to continue to generate income from operations and positive cash flow in future periods;
- loss of legal ownership or title to the asset;
- significant changes in our strategic business objectives and utilization of the asset(s); and
- the impact of significant negative industry or economic trends.

If the assets are considered to be impaired, the impairment we recognize is the amount by which the carrying value of the assets exceeds the fair value of the assets. Fair value is determined by a combination of third party sources and discontinued cash flows. In addition, we base the useful lives and related amortization or depreciation expense on our estimate of the period that the assets will generate revenues or otherwise be used by us. We also periodically review the lives assigned to our intangible assets to ensure that our initial estimates do not exceed any revised estimated periods from which we expect to realize cash flows from the technologies. If a change were to occur in any of the above-mentioned factors or estimates, the likelihood of a material change in our reported results would increase.

At December 31, 2012, the net book value of identifiable intangible assets that are subject to amortization totaled \$4,710,000 and the net book value of fixed assets totaled \$630,000.

We determined that, as of December 31, 2012 and 2011, there have been no significant events which may have affected the carrying value of TearLab® technology. However, our prior history of losses and losses incurred during the current fiscal year reflects a potential indication of impairment, thus requiring management to assess whether TearLab Research, Inc.'s technology was impaired as of December 31, 2012 and 2011. Based on management's estimates of forecasted undiscounted cash flows as of December 31, 2012 and 2011, we concluded that there was no indication of an impairment of the TearLab technology in either fiscal period.

### **Stock-based Compensation**

We use the fair value method to account for share-based payments in accordance with the authoritative guidance for stock compensation. The fair value of each option award is estimated on the date

of grant using a Black-Scholes-Merton option pricing model, or Black-Scholes model, that uses assumptions regarding a number of complex and subjective variables. These variables include, but are not limited to, our expected stock price volatility, actual and projected employee stock option exercise behaviors, risk-free interest rate and expected dividends. The Company's computation of expected volatility is based on the historical volatility of the Company's common stock over a period of time equal to the expected term of the stock options. Due to the lack of sufficient historical data, the Company's computation of expected life was estimated using the "short-cut approach" as provided in SAB No. 110 as options granted by the Company meet the criteria of "plain vanilla" options as defined in SAB No. 110. Under this approach, estimated life is calculated to be the mid-point between the vesting date and the end of the contractual period. The risk-free interest rates are based on the U.S. Treasury yield in effect at the time of the grant. Since we do not expect to pay dividends on our common stock in the foreseeable future, we estimated the dividend yield to be 0%. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. We estimate pre-vesting forfeitures based on our historical experience.

If factors change and we employ different assumptions for determination of fair value in future periods, the share-based compensation expense that we record may differ significantly from what we have recorded in the current period. There is a high degree of subjectivity involved when using option pricing models to estimate share-based compensation. Certain share-based payments, such as employee stock options, may expire worthless or otherwise result in zero intrinsic value as compared to the fair values originally estimated on the grant date and reported in our consolidated financial statements. Alternatively, values may be realized from these instruments that are significantly in excess of the fair values originally estimated on the grant date and reported in our consolidated financial statements. There is currently no market-based mechanism or other practical application to verify the reliability and accuracy of the estimates stemming from these valuation models, nor is there a means to compare and adjust the estimates to actual values. Although the fair value of employee share-based awards is determined in accordance with authoritative guidance on stock compensation using an option-pricing model, that value may not be indicative of the fair value observed in a willing buyer/willing seller market transaction.

As of December 31, 2012, \$2.472 million of total unrecognized compensation cost related to stock options is expected to be recognized over a weighted-average period of 2.83 years.

### ***Warrant liabilities***

The Company issued several rounds of warrants related to various debt and equity transactions that occurred in 2007, 2010 and 2011. The Company accounts for its warrants issued in accordance with US GAAP accounting guidance under ASC 815 applicable to derivative instruments, which requires every derivative instrument within its scope to be recorded on the balance sheet as either an asset or liability measured at its fair value, with changes in fair value recognized in earnings. Based on this guidance, the Company determined that the Company's warrants do not meet the criteria for classification as equity. Accordingly, the Company classified the warrants as current liabilities. The warrants are subject to remeasurement at each balance sheet date, with any change in fair value recognized as a component of other income (expense), net in the statements of operations. We estimated the fair value of these warrants at the respective balance sheet dates using the Black-Scholes option-pricing model as described in the stock-based compensation section above, based on the estimated market value of the underlying common stock at the valuation measurement date, the remaining contractual term of the warrant, risk-free interest rates and expected dividends on and expected volatility of the price of the underlying common stock. There is a moderate degree of subjectivity involved when using option pricing models to estimate warrant liability and the assumptions used in the Black-Scholes option-pricing model are moderately judgmental.

## **Income Taxes**

We recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The tax benefits recognized in the consolidated financial statements from such a position should be measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement. Rules under Section 382 of the U.S. Internal Revenue Code may substantially reduce our ability to utilize prior tax losses.

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the expected future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. We measure deferred tax assets and liabilities using the enacted tax rates expected to apply to taxable income in the years in which we expect to recover or settle those temporary differences. We recognize the effect of a change in tax rates on deferred tax assets and liabilities in income in the period that includes the enactment date. A valuation allowance is established when it is "more likely than not" the future realization of all or some of the deferred tax assets will not be achieved. For further explanation of our provision for income taxes, see Note 6, "Income Taxes".

For information on the recent accounting pronouncements impacting our business, see Note 2 of the Notes to Consolidated Financial Statements included in Item 8.

### ***ITEM 7A. Quantitative and Qualitative Disclosures about Market Risk.***

#### **Currency Fluctuations and Exchange Risk**

Our sales are denominated primarily in U.S. dollars with minimal sales in Euros and pounds sterling, while a minor portion of our expenses are in Canadian dollars, Australian dollars and Pounds sterling. Our purchases of test cards are in Australian dollars. We cannot predict any future trends in the exchange rate of the Canadian dollar, Australian dollar, Euro or Pound sterling against the U.S. dollar. Any strengthening of the Canadian dollar, Australian dollar, Euro or Pound sterling in relation to the U.S. dollar would increase the U.S. dollar cost of our operations, and affect our U.S. dollar measured results of operations. We maintain bank accounts in Canadian dollars, Australian dollars, Euros and Pound sterling to meet short term operating requirements. Based on the balances in the Canadian dollar, Australian dollar, Euro and Pound sterling denominated bank accounts at December 31, 2012, hypothetical increases of \$0.01 in the value of the Canadian dollar, the Australian dollar, the Euro and the Pound sterling in relation to the U.S. dollar would not have a material impact on our results of our operations. We do not engage in any hedging or other transactions intended to manage these risks. In the future, we may undertake hedging or other similar transactions or invest in market risk sensitive instruments if we determine that is advisable to offset these risks.

#### **Interest Rate Risk**

The primary objective of our investment activity is to preserve principal while maximizing interest income we receive from our cash resources, without increasing risk. We believe this will minimize our market risk. We do not use interest rate derivative transactions to manage our interest rate risk. We reduce our exposure to interest rate risk by investing in savings or money market accounts. Declines in interest rates over an extended period of time will reduce our interest income while an increase over an extended period of time will increase our interest income. A reduction of interest rate by 100 basis points over the 12 months ended December 31, 2012 would reduce interest income by \$30,000 to \$0.



**ITEM 8. Financial Statements and Supplementary Data.**

**Consolidated Financial Statements**

**REPORT OF INDEPENDENT REGISTERED**

**PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders of TearLab Corp.

We have audited the accompanying consolidated balance sheets of TearLab Corp. as of December 31, 2012 and 2011, and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2012. Our audits also included the financial statement schedule listed in the Index at Item 15(a). These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of TearLab Corp. at December 31, 2012 and 2011, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2012, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly, in all material respects the information set forth therein.

/s/ Ernst & Young LLP

San Diego, California  
March 25, 2013

**TearLab Corp.**

**CONSOLIDATED BALANCE SHEETS**  
*(in thousands, except share and per share data)*

	<b>As of December 31,,</b>	
	<b>2012</b>	<b>2011</b>
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents .....	\$ 15,437	\$ 2,807
Accounts receivable .....	889	321
Inventory .....	1,863	898
Prepaid expenses .....	387	190
Other current assets .....	60	35
<b>Total current assets</b> .....	<b>18,636</b>	<b>4,251</b>
Fixed assets, net.....	630	199
Patents and trademarks, net.....	136	164
Intangible assets, net .....	4,709	5,924
Other non-current assets .....	28	—
<b>Total assets</b> .....	<b>\$ 24,139</b>	<b>\$ 10,538</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities:</b>		
Accounts payable .....	\$ 1,067	\$ 218
Accrued liabilities .....	1,989	1,843
Obligations under warrants .....	6,239	2,957
<b>Total current liabilities</b> .....	<b>9,295</b>	<b>5,018</b>
Commitments and contingencies (Note 8)		
<b>Stockholders' equity:</b>		
Preferred Stock, \$0.001 par value, 10,000,000 authorized, none outstanding.....	—	—
Common Stock, \$0.001 par value, 65,000,000 authorized, 28,741,653 issued and outstanding at December 31, 2012 and 65,000,000 authorized, 20,414,993 issued and outstanding at December 31, 2011 .....	29	20
Additional paid-in capital .....	421,662	393,035
Accumulated deficit .....	(406,847)	(387,535)
<b>Total stockholders' equity</b> .....	<b>14,844</b>	<b>5,520</b>
<b>Total liabilities and stockholders' equity</b> .....	<b>\$ 24,139</b>	<b>\$ 10,538</b>

*See accompanying notes*

**TearLab Corp.**

**CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**

*(in thousands, except per share data)*

	Years ended December 31,		
	2012	2011	2010
Revenue .....	\$ 3,960	\$ 2,124	\$ 1,701
Cost of goods sold (excluding amortization of intangibles) .....	<u>2,295</u>	<u>1,626</u>	<u>849</u>
<b>Gross profit</b> .....	<u>1,665</u>	<u>498</u>	<u>852</u>
Operating expenses.....			
Amortization of intangibles assets.....	1,215	1,215	1,215
General and administrative.....	4,770	3,842	3,753
Clinical, regulatory and research & development .....	2,241	1,304	1,365
Sales and marketing .....	<u>5,471</u>	<u>2,195</u>	<u>1,463</u>
Total operating expenses .....	<u>13,697</u>	<u>8,556</u>	<u>7,796</u>
<b>Loss from operations</b> .....	<u>(12,032)</u>	<u>(8,058)</u>	<u>(6,944)</u>
<b>Other income (expenses)</b>			
Interest income .....	30	6	21
Changes in fair value of warrant obligations .....	(7,296)	94	701
Interest expense .....	—	(95)	(210)
Amortization of deferred financing charges, warrants & beneficial conversion values .....	—	(705)	(228)
Other, net .....	<u>(14)</u>	<u>(51)</u>	<u>(23)</u>
Total other income (expenses),.....	<u>(7,280)</u>	<u>(751)</u>	<u>261</u>
<b>Net loss and comprehensive loss</b> .....	<u>\$ (19,312)</u>	<u>\$ (8,809)</u>	<u>\$ (6,683)</u>
<b>Weighted average number of shares outstanding – basic and     diluted</b> .....	<u>25,490,186</u>	<u>17,744,736</u>	<u>14,097,973</u>
<b>Net loss per common share – basic and diluted</b> .....	<u>\$ (0.76)</u>	<u>\$ (0.50)</u>	<u>\$ (0.47)</u>

*See accompanying notes*

**TearLab Corp.**

**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**

*(in thousands, except share data)*

	Common stock		Additional paid-in capital	Accumulated deficit	Stockholders' equity
	Shares	Amount			
<b>Balance, December 31, 2009</b> .....	<b>9,866,685</b>	<b>\$ 10</b>	<b>\$ 378,790</b>	<b>\$ (372,043)</b>	<b>\$ 6,757</b>
Stock-based compensation.....	—	—	1,395	—	1,395
Shares issued in registered direct financing.....	1,552,795	2	3,616	—	3,618
Shares issued in PIPE financing .....	3,244,766	3	2,765	—	2,768
Shares issued to Marchant Securities for services provided in the PIPE financing.....	101,548	—	—	—	—
Options exercised .....	9,572	—	22	—	22
Net loss and comprehensive loss .....	—	—	—	(6,683)	(6,683)
<b>Balance, December 31, 2010</b> .....	<b>14,775,366</b>	<b>\$ 15</b>	<b>\$ 386,588</b>	<b>\$ (378,726)</b>	<b>\$ 7,877</b>
Stock-based compensation.....	—	—	490	—	490
Shares issued in convertible debt conversion .....	1,629,539	1	2,106	—	2,107
Shares issued in PIPE financing .....	3,846,154	4	3,545	—	3,549
Shares issued to Greybrook Capital for advisory services provided.....	163,934	—	306	—	306
Net loss and comprehensive loss .....	—	—	—	(8,809)	(8,809)
<b>Balance, December 31, 2011</b> .....	<b>20,414,993</b>	<b>\$ 20</b>	<b>\$ 393,035</b>	<b>\$ (387,535)</b>	<b>\$ 5,520</b>
Stock-based compensation.....	—	—	1,441	—	1,441
Warrants exercised .....	1,765,497	2	7,274	—	7,276
Shares issued in public and registered direct offerings.....	5,950,000	6	20,339	—	20,345
Restricted stock units issued.....	316,779	1	1,181	—	1,182
Issue costs of equity financings .....	—	—	(1,718)	—	(1,718)
Options exercised .....	294,384	—	110	—	110
Net loss and comprehensive loss .....	—	—	—	(19,312)	(19,312)
<b>Balance, December 31, 2012</b> .....	<b><u>28,741,653</u></b>	<b><u>\$ 29</u></b>	<b><u>\$ 421,662</u></b>	<b><u>\$ (406,847)</u></b>	<b><u>\$ 14,844</u></b>

*See accompanying notes*

**TearLab Corp.**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(in thousands)

	Years ended December 31,		
	2012	2011	2010
<b>OPERATING ACTIVITIES</b>			
Net loss for the year.....	\$ (19,312)	\$ (8,809)	\$ (6,683)
Adjustments to reconcile net loss to cash used in operating activities:			
Stock-based compensation.....	1,441	490	1,395
Depreciation of fixed assets.....	137	83	71
Amortization of patents and trademarks.....	28	28	28
Amortization of intangible assets.....	1,215	1,215	1,215
Amortization of deferred financing charges, warrants & beneficial conversion values.....	—	402	228
Non-cash interest accrued on convertible debt funding.....	—	96	210
Non-cash advisory fees paid to Greybrook in common shares.....	—	311	—
Non-cash bonuses paid to management in common shares.....	1,182	—	—
Warrant issuance costs.....	—	303	—
Change in fair value of warrant obligation.....	7,296	(94)	(701)
Gain on disposal of fixed assets.....	—	—	(3)
Net change in working capital and non-current asset balances related to operations.....	(787)	1	(300)
<b>Cash used in operating activities.....</b>	<b>(8,800)</b>	<b>(5,974)</b>	<b>(4,540)</b>
<b>INVESTING ACTIVITIES</b>			
Additions to fixed assets, net of proceeds.....	(569)	(156)	(55)
Cash used in investing activities.....	(569)	(156)	(55)
<b>FINANCING ACTIVITIES</b>			
Proceeds from the exercise of common stock options.....	110	—	22
Proceeds from issuance of shares in a public offering.....	12,420	—	—
Proceeds from issuance of shares in an underwritten registered financing.....	7,925	—	—
Proceeds from the exercise of warrants.....	3,262	—	—
Proceeds from issuance of shares and warrants in a private placement financing.....	—	7,000	3,000
Proceeds from issuance of shares and warrants in a registered financing.....	—	—	5,000
Costs of issuance of shares and warrants in private placement and registered direct financings.....	(1,718)	(789)	(807)
Cash provided by financing activities.....	21,999	6,211	7,215
Net increase in cash and cash equivalents during the year.....	12,630	81	2,620
Cash and cash equivalents, beginning of year.....	2,807	2,726	106
<b>Cash and cash equivalents, end of year.....</b>	<b>\$ 15,437</b>	<b>\$ 2,807</b>	<b>\$ 2,726</b>

*See accompanying notes*

## **TearLab Corp.**

### **Notes to Consolidated Financial Statements** (expressed in U.S. dollars except as otherwise noted)

#### **1. BASIS OF PRESENTATION**

*TearLab Corp.* ("TearLab" or the "Company"), a Delaware corporation, is an ophthalmic device company that is commercializing a proprietary in vitro diagnostic tear testing platform, the TearLab® test for dry eye disease, or DED, which enables eye care practitioners to test for highly sensitive and specific biomarkers using nanoliters of tear film at the point-of-care.

The accompanying consolidated financial statements include the accounts of the Company and all of its wholly owned subsidiaries. Intercompany accounts and transactions have been eliminated on consolidation.

The accompanying consolidated financial statements have been prepared on the going concern basis, which assumes that the Company will continue to operate as a going concern and which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. However, the Company has sustained substantial losses of \$19.3 million, \$8.8 million, and \$6.7 million for the years ended December 31, 2012, 2011, and 2010, respectively. The Company's working capital surplus at December 31, 2012 is \$9.3 million. Based on the Company's annual operating plan approved by the Board of Directors, management believes the Company's existing cash and cash equivalents of \$15.4 million at December 31, 2012 combined with anticipated cash flows provided by sales of its products in 2013 will be sufficient to fund its cash requirements through at least December 31, 2013.

A successful transition to attaining profitable operations is dependent upon obtaining sufficient financing to fund the Company's planned expenses and achieving a level of revenues adequate to support the Company's cost structure. The Company may be required to seek additional debt or equity financing to support its operations until it becomes cash flow positive. There can be no assurances that there will be adequate financing available to the Company on acceptable terms or at all. If the Company is not able to achieve its planned revenue or incurs costs in excess of its forecasts and is unable to obtain additional financing, the Company would need to significantly curtail or reorient its operations during 2013, which could have a material adverse effect on the Company's ability to achieve its business objectives. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts classified as liabilities that might be necessary should the Company be forced to take any such actions.

#### **2. SIGNIFICANT ACCOUNTING POLICIES**

##### ***Use of estimates***

The preparation of financial statements in conformity with U.S. Generally Accepted Accounting Principles ("GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenue and expenses during the reporting periods. Some of the Company's more significant estimates include those related to uncollectible receivables, inventory reserves, stock-based compensation, equity instruments and its intangible assets. Actual results could differ from those estimates.

## ***Concentrations and risk***

### ***Credit risk***

Financial instruments, which potentially subject the Company to concentrations of credit risk, consist primarily of cash and accounts receivable. The Company limits its exposure to credit loss by placing its cash with high credit quality financial institutions.

During fiscal 2012, the Company derived 100% of its revenue from the sale of the TearLab® Osmolarity product. Of the 2012 revenue, there were no customers with revenues in excess of 10%. Customers representing revenue in excess of 10% in prior years were:

	Years ended December 31,		
	2012	2011	2010
Alcon Research Ltd. ....	1%	11%	1%
Bon Optic VertriebsgesellschaftmbH.....	2%	10%	4%
The Technology Source.....	—	—	11%

Currently, there is only one supplier for each of the reader and pen components of the TearLab® Osmolarity System and the test cards.

### ***Fair value of financial instruments***

The Company's financial instruments consist principally of cash and cash equivalents, accounts receivable, accounts payable and accrued expenses. The carrying amounts of financial instruments such as cash equivalents, accounts receivable, accounts payable and accrued expenses approximate the related fair values due to the short-term maturities of these instruments.

### ***Cash and cash equivalents***

The Company considers all highly liquid investments that are readily convertible into cash and have an original maturity of three months or less at the time of purchase to be cash equivalents.

### ***Accounts receivable and allowance for doubtful accounts***

The Company's accounts receivable consist primarily of trade receivables from customers and are generally unsecured and due within 30 days. The carrying value of accounts receivable approximates their fair value due to their short term nature. The Company evaluates the collectability of its accounts receivable based on a combination of factors. Expected credit losses related to trade receivables are recorded as an allowance for doubtful accounts. The allowance for doubtful accounts is charged to sales and marketing expense and accounts receivable are written off as uncollectible and deducted from the allowance after appropriate collection efforts have been exhausted. To date, charges for bad debt expense have not been material.

### ***Inventory***

Inventory is recorded at the lower of cost (based on first in, first out basis) or market and consists of purchased finished goods. Inventory is periodically reviewed for evidence of slow-moving or obsolete items,

and the estimated reserve is based on management's reviews of inventories on hand, compared to estimated future usage and sales, reviewing product shelf-life, and assumptions about the likelihood of obsolescence.

### ***Fixed assets***

Property and equipment are carried at cost less accumulated depreciation and amortization. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, ranging from three to seven years. Maintenance and repairs are expensed as incurred. The Company reviews property and equipment for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. An impairment loss would be recognized when estimated future undiscounted cash flows relating to the asset are less than its carrying amount. An impairment loss is measured as the amount by which the carrying amount of an asset exceeds its fair value.

### ***Impairment of long-lived assets***

The Company periodically assesses the carrying value of intangible and other long-lived assets, and whenever events or changes in circumstances indicate that the carrying amount of an asset might not be recoverable. The assets are considered to be impaired if the Company determines that the carrying value may not be recoverable based upon its assessment, which includes consideration of the following events or changes in circumstances:

- the asset's ability to continue to generate income from operations and positive cash flow in future periods;
- loss of legal ownership or title to the asset;
- significant changes in the Company's strategic business objectives and utilization of the asset(s); and
- the impact of significant negative industry or economic trends.

If the assets are considered to be impaired, the impairment recognized is the amount by which the carrying value of the assets exceeds the fair value of the assets. Fair value is determined by a combination of data from third party sources and the application of discounted cash flow models to project cash flows from the asset. In addition, the Company bases the useful lives and related amortization or depreciation expense on an estimate of the period that the assets will generate revenues or otherwise be used. The Company also periodically reviews the lives assigned to long-lived assets to ensure that the initial estimates do not exceed any revised estimated periods from which the Company expects to realize cash flows from its assets.

### ***Patents and trademarks***

Patents and trademarks are recorded at historical cost and are amortized using the straight-line method over their estimated useful lives, not to exceed 15 years.

### ***Intangible Assets***

Intangible assets are recorded at historical cost and are amortized using the straight line-line method over their estimated useful life of 10 years.

### ***Product Warranties***

The Company generally provides a 12 month warranty on its TearLab® Osmolarity System and related disposables. The Company accrues the estimated cost of this warranty at the time revenue is recorded



and charges warranty expense to cost of goods sold. Warranty reserves are established based on historical experience with failure rates and the number of systems covered by warranty. Warranty reserves are depleted as systems and disposables are replaced. The Company reviews warranty reserves quarterly and, if necessary, make adjustments. The activities in the warranty reserve are as follows (in thousands):

	Years ended December 31,		
	2012	2011	2010
Balance at beginning of year .....	\$ 36	\$ 51	\$ 9
Charges to cost of goods sold .....	196	56	55
Costs applied to liability .....	(125)	(71)	(13)
Balance at end of year .....	<u>\$ 107</u>	<u>\$ 36</u>	<u>\$ 51</u>

### ***Income Taxes***

A deferred tax asset or liability is determined based on the difference between the financial statement and tax basis of assets and liabilities as measured by the enacted tax rates which will be in effect when these differences reverse. The Company provides a valuation allowance against net deferred tax assets unless, based upon the available evidence, it is more likely than not that the deferred tax assets will be realized.

### ***Revenue recognition***

Revenue is recognized when all four of the following criteria are met: (i) persuasive evidence that an arrangement exists; (ii) delivery of the products has occurred; (iii) the selling price is fixed or determinable; and (iv) collectability is reasonably assured. The Company's timing of revenue recognition is impacted by factors such as passage of title, payments and customer acceptance. Amounts received in excess of revenue recognizable are deferred.

The Company enters into contracts where revenue is derived from multiple deliverables containing a mix of products, which generally includes either the sale or the right to use a TearLab Osmolarity System and sales of a fixed number of test cards. The Company either sells readers and test cards as a combined unit with no future commitments on behalf of the client or allows the customer to use the readers with a commitment to fulfill a minimum purchase obligation, typically over a three year period. Revenue recognition for contracts with multiple deliverables is based on the individual units of accounting determined to exist in the contract. A delivered item is considered a separate unit of accounting when the delivered item has value to the customer on a stand-alone basis. Items are considered to have stand-alone value when they are sold separately by any vendor or when the customer could resell the item on a stand-alone basis. Considering that test cards are essential to the operation of a TearLab reader, there is no alternative vendor for the test cards and no indication that a secondary market for the TearLab readers is established, the deliverables under the contracts entered into during 2012 and 2011 do not meet criteria for separation under the multiple-element arrangements guidance. Consideration is allocated at the inception of the contract to all deliverables based on their relative selling price. The relative selling price for each deliverable is determined using vendor specific objective evidence (VSOE) of selling price or third-party evidence of selling price if VSOE does not exist. If neither VSOE nor third-party evidence exists, the Company uses its best estimate of the selling price for the deliverable. The Company recognizes revenue for each of the elements only when it determines that all applicable recognition criteria have been met.

Subsequent to its launch in the fourth quarter of 2008, the Company's revenues have been derived from sales of the TearLab® Osmolarity System for Dry Eye Disease ("DED") which consists of hardware and related disposables of the TearLab System. The Company's sales are currently to countries in North America,

Europe, and Asia, and are generally transacted through distributors. The Company records revenue when all of its obligations are completed which is generally upon shipment of the Company's products.

The Company typically has a no return policy for its products, the Company has established a return reserve for product sales that contain an implicit right of return. The reserve of \$71,000 and \$10,000 as of December 31, 2012 and 2011, respectively, reduces revenue and is included in accrued liabilities.

#### ***Cost of goods sold***

Cost of goods sold includes the costs the Company incurs for the purchase of the TearLab® Systems sold and related freight and shipping costs, fees related to warehousing and logistics inventory management associated with conducting business. The Company recorded \$255,000, \$187,000 and \$142,000 in shipping and handling fees for the years ended December 31, 2012, 2011 and 2010, respectively.

#### ***Clinical, regulatory and research & development costs***

Clinical and regulatory costs attributable to the performance of contract services are recognized as an expense as the services are performed. Non-refundable, up-front fees paid in connection with these contracted services are deferred and recognized as an expense over the estimated term of the related contract.

#### ***Stock-based compensation***

The Company accounts for stock-based compensation expense for its employees in accordance with US GAAP guidance related to stock-based compensation. Under this guidance, stock-based compensation cost is estimated at the grant date based on the fair value of the award and is recognized as an expense ratably over the requisite service period of the award. The Company uses the Black-Scholes option-pricing model for determining the fair value for all its awards and will recognize compensation cost on a straight-line basis over the awards' vesting periods.

#### ***Warrant liabilities***

The Company issued several rounds of warrants related to various debt and equity transactions which occurred in 2010 and 2011. The Company accounts for its warrants issued in accordance with US GAAP accounting guidance applicable to derivative instruments, which requires every derivative instrument within its scope to be recorded on the balance sheet as either an asset or liability measured at its fair value, with changes in fair value recognized in earnings. Based on this guidance, the Company determined that the Company's warrants do not meet the criteria for classification as equity. Accordingly, the Company classified the warrants as current liabilities. The warrants are subject to re-measurement at each balance sheet date, with any change in fair value recognized as a component of other income (expense), in the statements of operations and comprehensive loss. The Company estimated the fair value of these warrants at the respective balance sheet dates using the Black-Scholes option-pricing model as described in the stock-based compensation section above, based on the estimated market value of the underlying common stock at the valuation measurement date, the remaining contractual term of the warrant, risk-free interest rates and expected dividends on and expected volatility of the price of the underlying common stock. There is a moderate degree of subjectivity involved when using option pricing models to estimate warrant liability and the assumptions used in the Black-Scholes option-pricing model are moderately judgmental.

### **Foreign currency transactions**

The Company's functional and reporting currency is the U.S. dollar. The assets and liabilities of the Company's Canadian operations are maintained in U.S. dollars. Monetary assets and liabilities denominated in foreign currencies are translated into U.S. dollars at exchange rates in effect at the consolidated balance sheet dates, and non-monetary assets and liabilities are translated at exchange rates in effect on the date of the transaction. Revenue and expenses are translated into U.S. dollars at average exchange rates prevailing during the year. Resulting exchange gains (losses) of: (\$15,000), (\$29,000), \$(34,000) are included in other income (expense) in the years ended December 31, 2012, 2011 and 2010, respectively.

### **Geographic information**

The following table provides geographic information related to the Company's revenues (*in thousands*):

	<u>United States</u>	<u>Canada</u>	<u>Rest of World</u>	<u>Total</u>
<b>December 31, 2012</b> .....				
Revenues.....	\$ 3,564	\$ 59	\$ 337	\$ 3,960
December 31, 2011.....				
Revenues.....	\$ 1,347	\$ 71	\$ 706	\$ 2,124

### **Comprehensive loss**

Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Comprehensive income (loss) generally includes unrealized gains or losses on the Company's marketable securities and foreign currency translation adjustments. In all the periods presented, the Company's comprehensive loss equaled net loss for the period.

### **Net loss per share**

Basic earnings per share ("EPS") excludes dilutive securities and is computed by dividing net loss available to common stockholders by the weighted average number of shares of common stock outstanding for the year. Diluted EPS reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted and the resulting additional shares are dilutive because their inclusion decreases the amount of EPS.

The following are potentially dilutive securities which have not been used in the calculation of diluted loss per share as they are anti-dilutive (in thousands):

	<u>December 31,</u>		
	<u>2012</u>	<u>2011</u>	<u>2010</u>
Stock options.....	4,100	3,691	3,577
Shares reserved for issuance on conversion of debt obligations.....	—	—	1,327
Warrants to be issued on conversion of debt obligations.....	—	—	109
Warrants.....	2,183	4,087	753
Total.....	<u>6,283</u>	<u>7,778</u>	<u>5,766</u>

### Recent accounting pronouncements

In June 2011, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2011-05, *Comprehensive Income (Topic 220)—Presentation of Comprehensive Income*. ASU 2011-05 amends the presentation of comprehensive income to allow an entity the option to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. In both options, the entity is required to present each component of net income along with total net income, each component of other comprehensive income along with a total for other comprehensive income, and a total amount for comprehensive income. The guidance eliminates the option to present the components of other comprehensive income as part of the statement of changes in stockholders' equity. In December 2011, the FASB issued ASU 2011-12 which defers certain provisions of ASU 2011-05. Under ASU 2011-12, the provision to require entities to present reclassification adjustments out of accumulated other comprehensive income by component in both the statement of operations and the statement of equity was deferred indefinitely. During the deferral period, entities will be required to comply with all existing requirements for reclassification adjustments. The Company adopted these standards on January 1, 2012, which did not have an impact on the Company's financial results or disclosures, but will have an impact on the presentation of comprehensive income.

### 3. BALANCE SHEET DETAILS

#### Accounts receivable

(in thousands)	December 31,	
	2012	2011
Trade receivables.....	\$ 909	\$ 354
Due from related parties .....	15	4
Allowance for doubtful accounts.....	(36)	(42)
Other receivables .....	1	5
	<u>\$ 889</u>	<u>\$ 321</u>

#### Inventory

(in thousands)	December 31,	
	2012	2011
Finished goods.....	\$ 1,863	\$ 1,499
Inventory reserves.....	—	(601)
	<u>\$ 1,863</u>	<u>\$ 898</u>

The Company evaluates inventory for estimated excess quantities and obsolescence, based on expected future sales levels and projections of future demand, with the excess inventory provided for. In addition, the Company assesses the impact of changing technology and market conditions. The Company has entered into a long term purchase commitment to buy the test cards from MiniFAB. The purchase commitment contains required minimum annual purchases. As part of our consideration of excess or obsolete inventory, the Company considers future annual minimum purchases, estimated future usage and the expiry dating of the cards in its analysis of any inventory reserve needed. The usage of the minimum purchase commitment is predicated upon significant increases in revenues from TearLab products as compared to 2012 and prior years.

**Prepaid expenses**

(in thousands)	December 31,	
	2012	2011
Prepaid trade shows .....	\$ 159	\$ 25
Prepaid insurance.....	131	119
Other fees and services .....	97	46
	<u>\$ 387</u>	<u>\$ 190</u>

**Fixed Assets**

(in thousands)	December 31,	
	2012	2011
Furniture and office equipment .....	\$ 115	\$ 49
Computer equipment and software.....	203	165
Demo equipment .....	58	53
Rental equipment.....	524	103
Medical equipment .....	373	335
	1,273	705
Accumulated depreciation .....	(643)	(506)
	<u>\$ 630</u>	<u>\$ 199</u>

Depreciation expense was \$137,000, \$83,000, and \$71,000, during the years ended December 31, 2012, 2011, and 2010, respectively.

**Patents and trademarks**

(in thousands)	December 31,	
	2012	2011
Patents .....	\$ 236	\$ 236
Trademarks .....	32	32
	268	268
Accumulated amortization.....	(132)	(104)
	<u>\$ 136</u>	<u>\$ 164</u>

Amortization expense was \$28,000, \$28,000, and \$28,000 during the years ended December 31, 2012, 2011, and 2010, respectively.

These patents and trademarks are amortized, using the straight-line method, over an estimated useful life of 10 years from the date of approval of the patents and trademarks.

Estimated aggregate amortization expense for patents and trademarks at December 31, 2012 is as follows (in thousands):

2013 .....	\$ 28
2014 .....	28
2015 .....	28
2016 .....	28
Thereafter .....	24
Total.....	<u>\$ 136</u>

### Accrued liabilities

(in thousands)	December 31,	
	2012	2011
Due to professionals .....	\$ 258	\$ 295
Due to employees and directors.....	1,052	1,080
Clinical trial accruals .....	—	174
Other .....	679	294
	<u>\$ 1,989</u>	<u>\$ 1,843</u>

### 4. INTANGIBLE ASSETS

The Company's intangible assets consist of the value of TearLab® Technology acquired in the acquisition of TearLab Research, Inc. The TearLab Technology consists of a disposable lab card and card reader, supported by an array of patents and patent applications that are either held or in-licensed by the Company. The TearLab Technology is being amortized using the straight-line method over an estimated useful life of 10 years. Amortization expense for each of the years ended December 31, 2012, 2011 and 2010 was \$1,215,000.

Intangible assets subject to amortization consist of the following (in thousands):

	December 31, 2012		December 31, 2011	
	Cost	Accumulated Amortization	Cost	Accumulated Amortization
TearLab® technology .....	\$ 12,172	\$ 7,463	\$ 12,172	\$ 6,248

Estimated future amortization expense related to intangible assets with finite lives at December 31, 2012 is as follows (in thousands):

	Amortization of intangible assets
2013 .....	1,215
2014 .....	1,215
2015 .....	1,215
2016 .....	1,064
Total.....	<u>\$ 4,709</u>

The Company determined that, as of December 31, 2012, there have been no significant events which may affect the carrying value of its TearLab technology. However, the Company's prior history of losses and losses incurred during the current fiscal year reflect a potential indication of impairment, thus requiring management to assess whether the Company's TearLab technology was impaired as of December 31, 2012. Based on management's estimates of forecasted undiscounted cash flows as of December 31, 2012, the Company concluded that there is no indication of an impairment of the Company's TearLab technology. Therefore, no impairment charge was recorded during any of the three years ended December 31, 2012.

### 5. RELATED PARTY TRANSACTIONS

On August 20, 2009, the Company entered into a distribution agreement with Science with Vision, pursuant to which Science with Vision obtained exclusive Canadian distribution rights with respect to the Company's products. The Company began selling products through the Canadian distributor in 2010. Sales

to this distributor for the years ended December 31, 2012 and 2011 were \$59,000 and \$71,000, respectively, and the outstanding accounts receivable balances due at December 31, 2012 and 2011 were \$15,000 and \$4,000, respectively. The Company's chairman of the board of directors and chief executive officer has a material financial interest in Science with Vision.

On November 2, 2009, the Company, entered into a capital advisory agreement for a two year period with Greybrook Capital Inc., or Greybrook, which was amended on January 8, 2010. Pursuant to the terms of the agreement, as amended, Greybrook was to receive \$200,000 in cash or 163,934 common shares for its services. On April 14, 2011 the Company issued 163,934 common shares to Greybrook to satisfy the outstanding liability related to both years. The Company's chairman of the board of directors and chief executive officer, is a principal with, and holds a material financial interest in Greybrook.

## 6. INCOME TAXES

Significant components of the Company's deferred tax assets and liabilities are as follows (*in thousands*):

	December 31,	
	2012	2011
<b>Deferred tax assets</b>		
Intangible assets.....	\$ 345	\$ 299
Stock options .....	5,643	5,017
Accruals and other .....	519	859
Net operating loss carry forwards.....	11,240	7,328
	<u>17,747</u>	<u>13,503</u>
Valuation allowance .....	<u>(15,838)</u>	<u>(11,158)</u>
<b>Deferred tax asset</b> .....	1,909	2,345
<b>Deferred tax liability</b> .....		
Intangible assets.....	<u>(1,909)</u>	<u>(2,345)</u>
<b>Deferred tax liability</b> .....	<u>(1,909)</u>	<u>(2,345)</u>
<b>Deferred taxes, net</b> .....	<u>\$ —</u>	<u>\$ —</u>

The following is a reconciliation of the recovery of income taxes between those that are expected, based on enacted tax rates and laws, to those currently reported (*in thousands*):

	December 31,		
	2012	2011	2010
<b>Loss for the year before income taxes</b> .....	<u>\$ (19,312)</u>	<u>\$ (8,809)</u>	<u>\$ (6,683)</u>
Expected recovery of income taxes .....	(7,829)	(3,487)	(2,654)
Stock-based compensation.....	64	103	97
Warrants .....	2,958	82	(278)
Non-deductible interest.....	—	38	83
Deferred state tax rate adjustment .....	(92)	30	47
Adjustment to deferred assets.....	187	1,236	(48)
Non-deductible expenses & other.....	32	69	44
Change in valuation allowance.....	4,680	1,929	2,709
<b>Total recovery of income taxes</b> .....	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

Income taxes are recorded in accordance with authoritative guidance for accounting for income taxes, which requires the recognition of deferred tax assets and liabilities to reflect the future tax consequences of events that have been recognized in the Company's consolidated financial statements or tax returns. Measurement of the deferred items is based on enacted tax laws. In the event of differences between financial reporting bases and tax bases of the Company's assets the probability of being able to realize the future benefits indicated by such assets is required. The Company records a valuation allowance to reduce the deferred tax assets to the amount that is more likely than not to be realized. Management has considered future taxable income and ongoing tax planning strategies in assessing the need for the valuation allowance. In the event the Company were to determine that it would be able to realize the deferred tax assets in the future in excess of their net recorded amounts, an adjustment to the deferred tax assets would increase the income in the period such determination was made. Likewise, should the Company determine that it would not be able to realize all or part of the net deferred tax assets in the future, an adjustment to the deferred tax assets would be charged to income in the period such determination was made.

In July 2006, the "FASB" issued additional guidance which requires the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. Additionally, the provisions under this guidance also provides guidance on derecognition, measurement, classification, interest and penalties, accounting in interim periods, disclosure and transition. The Company adopted the provisions under this guidance on January 1, 2007. The adoption of these provisions had no impact on the Company's consolidated financial position or results of operations. At December 31, 2012 and 2011, the Company's unrecognized income tax benefits and uncertain tax provisions were not material and would not, if recognized, affect the effective tax rate. As of December 31, 2012 and 2011 the Company had no unrecognized tax benefits.

During the year ended December 31, 2012, a change of ownership for tax purposes causing Section 382 restrictions on the utilization of net operating losses may have occurred. The Company is in the process of finalizing the roll forward of the Section 382 analysis, however, even if an ownership change occurred in 2012, the annual limitation on the utilization of net operating losses will not cause the carryforwards generated after the last ownership change in October 2008 to expire unused. In general, an ownership change, as defined by Section 382, results from transactions increasing ownership of certain stockholders or public groups in the stock of the corporation by more than 50 percentage points over a three-year period. Utilization of the net operating loss carryforwards will be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986, and similar state provisions due to ownership change limitations that have occurred. These ownership changes will limit the amount of net operating loss carryforwards that can be utilized to offset future taxable income.

At December 31, 2012, the Company had federal net operating loss carryforwards of approximately \$100.4 million, of which \$70.7 million will expire unused due to the 382 limitation, and California net operating loss carryforwards of approximately \$35.6 million, of which \$15.2 million will expire unused due to the 382 limitation. The federal net operating loss carryforwards begin to expire in 2018, and the California net operating loss carryforwards begin to expire in 2015. At December 31, 2012, approximately \$1.1 million of the net operating loss carryforwards relate to stock option exercises, which will result in an increase to additional paid-in capital and a decrease in income taxes payable at the time when the tax loss carryforwards are utilized.

The Company's policy is to recognize interest and penalties related to income tax matters in other expense. Because the Company has generated net operating losses since inception for both state and federal purposes, no additional tax liability, penalties or interest have been recognized for balance sheet or income statement purposes as of and for the three years ended December 31, 2012.



The Company does not expect a significant change in the amount of its unrecognized tax benefits within the next 12 months. Therefore, it is not expected that the change in the Company's unrecognized tax benefits will have a significant impact on the Company's results of operations or financial position.

All of the federal income tax returns for the Company and its subsidiaries remain open since their respective dates of incorporation due to the existence of net operating losses. The Company and its subsidiaries have not been, nor are they currently, under examination by the Internal Revenue Service or the Canada Revenue Agency.

State and provincial income tax returns are generally subject to examination for a period of between three and five years after their filing. However, due to the existence of net operating losses, all state income tax returns of the Company and its subsidiaries since their respective dates of incorporation are subject to re-assessment. The state impact of any federal changes remains subject to examination by various states for a period of up to one year after formal notification to the states. The Company and its subsidiaries have not been, nor are they currently, under examination by any state tax authority.

## **7. CONVERTIBLE NOTES PAYABLE AND ACCRUED INTEREST**

In July 2009, the Company entered into an agreement with certain investors whereby the investors agreed to provide financing (the "Financing") to the Company through the purchase of convertible secured notes ("the Notes"), in the aggregate amount of \$1.55 million. On August 31, 2009, an additional \$200,000 of financing was received by the Company to bring the aggregate total funding received to \$1.75 million. The Notes evidencing the Financing, were to mature on the second anniversary of their issuance ("the Maturity Date"), bearing interest at a rate of 12% per annum and were convertible into shares of the Company's common stock upon the request of holders of 51% or more of the outstanding principal amount of the Notes at any time after August 31, 2009 and prior to the Maturity Date. The conversion price of the Notes was \$1.3186. The Notes were secured by substantially all of the assets of the Company.

On June 13, 2011 (Conversion date), upon the request of holders of more than 51% of the outstanding principal amount of the Notes, the Company issued 1,629,539 shares of its common stock in consideration of the conversion and retirement of the Company's outstanding Financing obligations in the aggregate amount of \$2,149,000, of which \$399,000 is accrued interest through the Conversion date, (the Conversion). In connection with the Conversion, the Company issued warrants with a life of five years to purchase 109,375 shares of common stock (the "Financing Warrants"). The exercise price of the Financing Warrants is \$1.60 per common share. The fair value of the warrants totaling \$163,000, calculated using the Black-Scholes value model, was initially recorded at the date of Financing in additional paid-in capital and accreted over the term of the Notes through the Conversion date. The Company recorded amortization charges related to the Financing Warrants of \$0, \$69,000 and \$41,000 for the years ended December 31, 2012, 2011 and 2010, respectively, included in other income (expense).

As the conversion price of the Notes reflected a price discounted from the fair market value of the Company's common stock, there was a deemed beneficial conversion feature associated with the Financing. The Company recorded \$728,000 representing the value of the beneficial conversion feature at the date of the Financing in additional paid-in capital. The value of the beneficial conversion was being amortized over the term of the Notes through the Conversion date with charges \$0, \$314,000 and \$177,000 for the years ended December 31, 2012, 2011 and 2010, respectively, included in other income (expense).

The Company incurred \$87,000 in legal and consulting expenses related to the Financing which was allocated to deferred finance charges for \$43,000 and cost of equity for \$44,000 in proportion to the allocation of the Financing amount between equity and liabilities. The value of the deferred charges was amortized over

the term of the Notes through the Conversion date and expenses of \$0, \$19,000 and \$10,000 for the years ended December 31, 2012, 2011 and 2010, respectively, are included in other income (expense).

## 8. COMMITMENTS AND CONTINGENCIES

### Commitments

The Company has commitments relating to operating leases recognized on a straight line basis over the term of the lease for rental of office space and equipment from unrelated parties, expiring at various times from January 1, 2012 through June 30, 2018. The total future minimum obligation under these various leases for 2013, 2014, 2015, 2016, 2017 and 2018 is \$144,000, \$229,000, \$307,000, \$314,000, \$324,000 and \$162,000, respectively. Rent expensed under these leases was \$143,000, \$142,000, and \$145,000 for the years ended December 31, 2012, 2011, and 2010, respectively.

On March 12, 2003, TearLab entered into a patent license and royalty agreement with the University of California San Diego to obtain an exclusive license to make, use, sell, offer for sale, and import TearLab technology in development. Starting in 2009, the Company was required to make minimum royalty payments of \$35,000 or 5.5% of gross sales per year, whichever is higher. However, if this new technology is combined with existing technology, the maximum royalty payable on the sale of the combined products would be 5.5% of gross sales per year. As the new technology is currently in development, there is no revenue and the minimum royalty payment of \$35,000 is applicable. Future minimum royalty payments under this agreement as of December 31, 2012 are approximately as follows (in thousands):

2013 .....	\$	35
2014 .....		35
2015 .....		35
2016 .....		35
2017 .....		35
Thereafter .....		350
Total.....	\$	<u>525</u>

Effective October 1, 2006, TearLab entered into a patent license and royalty agreement with the University of California San Diego to obtain a second exclusive license to make, use, sell, offer for sale, and import existing TearLab technology. The Company is required to make royalty payments of \$35,000 or 5.5% of gross sales per year, whichever is higher. Additionally, the Company is required to pay a royalty of 30% of any sublicense fees it receives prior to receiving FDA approval and 25% of any sub-license fees it receives after FDA approval. The Company incurred fees of \$213,000, \$145,000 and \$99,000 under this agreement during the years ended December 31, 2012, 2011 and 2010, respectively. The Company had \$122,000 and \$61,000 in accrued royalties at December 31, 2012 and 2011, respectively. Future minimum royalty payments under this agreement as of December 31, 2012 are approximately as follows (in thousands):

2013 .....		35
2014 .....		35
2015 .....		35
2016 .....		35
2017 .....		35
Thereafter .....		350
Total.....	\$	<u>525</u>

On February 23, 2009, the Company entered into an agreement for the manufacturing of its TearLab® reader and pens with a third party manufacturing company. The agreement is in effect for three years after the start of production and can be renewed for one-year. The Company has no minimum commitment. Upon termination or cancellation of the agreement, the Company is liable for inventory and materials remaining at the manufacturer's facilities at 110% of the manufacturer's cost. At December 31, 2012, the manufacturer maintained inventory and materials with a value of approximately \$54,000, all of which had been purchased to meet manufacturing requirements of purchase orders issued by the Company.

On August 1, 2011, the Company, through its subsidiary, TearLab Research, Inc., entered into a manufacturing and development agreement, or the Manufacturing Agreement, with MiniFAB (Aust) Pty Ltd, or MiniFAB. Pursuant to the terms of the Manufacturing Agreement, MiniFAB will manufacture and supply test cards for the Company. The Manufacturing Agreement specifies minimum order quantities that will require the Company to purchase approximately \$31.3 million (AUD\$30.2 million) in test cards from MiniFAB from inception of the agreement through the end of 2015. The agreement is denominated in AUD\$ so the actual amounts paid in USD may vary. The agreement also has annual minimum order commitments under the Manufacturing Agreement. The Company met the annual minimum order commitment for the year ended December 31, 2012 and had no purchase obligation under the Manufacturing Agreement as of December 31, 2012. The Company has a commitment for 2013 of \$5.7 million representing a minimum commitment to purchase 1,700,000 test cards. The Manufacturing Agreement has a ten year initial term and may be terminated by either party if the other party is in breach or becomes insolvent. If terminated for any reason other than a default by MiniFAB, the Company will be obligated to pay a termination fee based on the cost of products manufactured by MiniFAB, but not yet invoiced, repayment of capital invested by MiniFAB, less depreciation calculated in accordance with Australian accounting standards, and the expected profit to MiniFAB had the remaining minimum order quantities been purchased by the Company.

Future minimum purchase commitments under this agreement as of December 31, 2012 are approximately as follows (in millions):

2013 .....	\$	5.7
2014 .....		9.7
2015 .....		<u>10.7</u>
Total.....	\$	<u>26.1</u>

### ***Contingencies***

During the ordinary course of business activities, the Company may be contingently liable for litigation and a party to claims. Currently the Company is not party to any litigation.

### **9. FAIR VALUE MEASUREMENTS**

The Company measures certain assets and liabilities in accordance with authoritative guidance which requires fair value measurements be classified and disclosed in one of the following three categories:

- Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities.
- Level 2: Observable prices that are based on inputs not quoted on active markets, but corroborated by market data.
- Level 3: Unobservable inputs are used when little or no market data is available.

As of December 31, 2012 and 2011, assets and liabilities are classified based on the lowest level of input that is significant to the fair value measurements. The Company reviews the fair value hierarchy classification on a quarterly basis. Changes in the ability to observe valuation inputs may result in a reclassification of levels for certain securities within the fair value hierarchy. The Company did not have any assets or liabilities in Level 1 and Level 2, and no transfers to or from Level 3 of the fair value measurement hierarchy during the years ended December 31, 2012 and 2011.

At December 31, 2012, the Company has a liability for warrants to purchase 2,095,685 shares of common stock at an exercise price of \$1.86 per share valued at \$6,239,000 (Note 10). All warrant liabilities are classified as Level 3 fair value measurements.

The following table provides a reconciliation for all liabilities measured at fair value using significant unobservable inputs (Level 3) for the year ended December 31, 2012 (in thousands):

	<b>Fair Value Measurements Using Significant Unobservable Inputs (Level 3)</b>
Balance of warrant liability at January 1, 2012 .....	\$ 2,957
Warrant exercises .....	(4,014)
Change in fair value of warrant liability included in other (income) / expense.....	7,296
Balance of warrant liability at December 31, 2012 .....	\$ 6,239

## **10. CAPITAL STOCK**

### **(a) Authorized share capital**

The total number of authorized shares of common stock of the Company is 65,000,000. Each share of common stock has a par value of \$0.001 per share. The total number of authorized shares of preferred stock of the Company is 10,000,000. Each share of preferred stock has a par value of \$0.001 per share.

### **(b) Common stock**

On April 14, 2011 pursuant to the capital advisory agreement (Note 5), as amended, the Company issued 163,934 shares of common stock to Greybrook. Elias Vamvakas, Chairman of the Company's board of directors and acting Chief Executive Officer, is a principal with, and holds a material financial interest in, Greybrook.

On June 13, 2011, the Company issued 1,629,539 shares of its common stock as well as warrants ("Financing Warrants") to purchase 109,375 shares of its common stock in consideration of conversion and retirement of the Company's outstanding July and August 2009 debt obligations and related accrued interest in the aggregate amount of \$2,149,000 with associated costs of \$41,000. The exercise price of the Financing Warrants is \$1.60 per common share representing the price per share equal to the closing bid price per share of the Company's common stock on the NASDAQ stock market on July 15, 2009.

On June 30, 2011, the Company closed a private placement financing in which 3,846,154 shares of common stock and warrants to purchase 3,846,154 shares of common stock for gross proceeds of approximately \$7,000,000 were issued, with associated costs of \$703,000, of which \$303,000 was related to

warrants and \$400,000 to common shares. Of the gross proceeds \$3,549,000 were recorded as share equity and the remaining \$3,451,000 was determined to be the value of the warrants issued in the financing. The investors purchased the shares and warrants for \$1.82 per unit (each unit consisting of one share and one warrant to purchase shares of common stock). The exercise price of the warrants is \$1.86 per share. The warrants are exercisable at any time from the date of issuance until June 30, 2016. During 2012, 1,750,469 warrants were exercised for gross proceeds of \$3,256,000.

On April 16, 2012, the Company closed an underwritten public offering of 3.45 million shares of its common stock at a price to the public of \$3.60 per share. The Company received gross proceeds of \$12,420,000, with associated costs of \$1,194,000.

On July 18, 2012, the Company closed an underwritten registered direct financing of 2.5 million shares of its common stock at a price of \$3.17 per share. The Company received gross proceeds of \$7,925,000, with associated costs of \$524,000.

On September 17, 2012 the Company issued 316,779 shares of restricted stock units to its management team as settlement of an outstanding liability for previously accrued bonuses related to achievement of CLIA waiver status. The costs basis of the shares granted was \$3.72, the closing price of the Company's stock on the date of grant, for a total value of \$1,182,000. The shares were issued in accordance with the Company's amended 2002 Stock Incentive Plan and were fully vested on the date of grant.

#### ***(c) Stock Option Plan***

The Company has a stock option plan, the 2002 Stock Incentive Plan (the "Stock Incentive Plan"), which was most recently amended on June 6, 2012 in order to increase the shares reserved under the Stock Option Plan by 1,000,000. Under the Stock Incentive Plan, up to 4,200,000 options are available for grant to employees, directors and consultants. Options granted under the Stock Incentive Plan may be either incentive stock options or non-statutory stock options. Under the terms of the Stock Incentive Plan, the exercise price per share for an incentive stock option shall not be less than the fair market value of a share of stock on the effective date of grant and the exercise price per share for non-statutory stock options shall not be less than 85% of the fair market value of a share of stock on the date of grant. No option granted to a holder of more than 10% of the Company's common stock shall have an exercise price per share less than 110% of the fair market value of a share of stock on the effective date of grant.

Options granted are typically service-based options. Generally, options expire 10 years after the date of grant. No incentive stock options granted to a 10% owner optionee shall be exercisable after the expiration of five years after the effective date of grant of such option, no option granted to a prospective employee, prospective consultant or prospective director may become exercisable prior to the date on which such person commences service, and with the exception of an option granted to an officer, director or consultant, no option shall become exercisable at a rate less than 20% per annum over a period of five years from the effective date of grant of such option unless otherwise approved by the Board.

The Company accounts for stock-based compensation under the authoritative guidance which requires that share-based payment transactions with employees be recognized in the financial statements based on their fair value and recognized as compensation expense over the vesting period. The Company uses the Black Scholes Merton model to calculate the fair value of the stock options. The weighted-average fair value of stock options granted during the years ended December 31, 2012, 2011 and 2010 was \$2.93, \$1.20, and \$1.69, respectively.

The following table sets forth the total stock-based compensation expense resulting from stock options included in the Company's consolidated statements of operations (in thousands):

	Year ended December 31,		
	2012	2011	2010
General and administrative .....	\$ 528	\$ 340	\$ 1,051
Clinical and regulatory .....	375	93	202
Sales and marketing .....	538	57	142
Stock-based compensation expense before income taxes .....	<u>\$ 1,441</u>	<u>\$ 490</u>	<u>\$ 1,395</u>

The estimated fair value of stock options for the periods presented was determined using the Black-Scholes option-pricing model with the following weighted-average assumptions:

	Year ended December 31,		
	2012	2011	2010
Volatility .....	104%	105%	112%
Weighted average Expected life of options (years) .....	5.74	5.36	5.55
Risk-free interest rate .....	0.88%	1.49%	2.12%
Dividend yield .....	0%	0%	0%

The Company's computation of expected volatility is based on the historical volatility of the Company's common stock over a period of time equal to the expected term of the stock options. Due to the lack of sufficient historical data, the Company's computation of weighted average expected life was estimated using the simplified method as prescribed by the Securities and Exchange Commission. Under this approach, estimated life is calculated to be the mid-point between the vesting date and the end of the contractual period. The risk-free interest rate for an award is based on the U.S. Treasury yield curve with a term equal to the expected life of the award on the date of grant.

A summary of the options issued during the year ended December 31, 2012 and the total number of options outstanding as of that date and changes since December 31, 2009 are set forth below:

	Number of Options Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (years)	Aggregate Intrinsic Value
Outstanding, December 31, 2009 .....	3,356,507	3.59	8.01	\$ 304,471
Granted .....	284,383	2.14		
Exercised .....	(9,572)	2.25		
Forfeited/cancelled/expired .....	(54,775)	5.51		
Outstanding, December 31, 2010 .....	3,576,543	3.46	7.18	\$ 899,010
Granted .....	238,278	1.56		
Exercised .....	—	—		
Forfeited/cancelled/expired .....	(124,167)	3.14		
Outstanding, December 31, 2011 .....	3,690,654	3.34	7.06	\$ 269,587
Granted .....	720,250	3.69		
Exercised .....	(294,384)	0.37		
Forfeited/cancelled/expired .....	(17,178)	10.37		
<b>Outstanding, December 31, 2012 .....</b>	<u>4,099,342</u>	<u>3.54</u>	<u>7.14</u>	<u>\$ 6,798,973</u>
<b>Vested or expected to vest, December 31,</b>				
<b>2012 .....</b>	<u>3,536,503</u>	<u>3.39</u>	<u>6.38</u>	<u>\$ 6,524,568</u>
<b>Exercisable, December 31, 2012 .....</b>	<u>3,469,569</u>	<u>3.39</u>	<u>6.33</u>	<u>\$ 6,469,114</u>

The aggregate intrinsic value at December 31, 2012 represents the total pre-tax intrinsic value, calculated as the difference between the Company's closing stock price on the last trading day of the respective fiscal year and the exercise price, multiplied by the number of shares that would have been received by the option holders if the options that could be exercised had been exercised on such date.

Net cash proceeds from the exercise of common stock options were \$110,000, \$0 and \$22,000 for the years ended December 31, 2012, 2011 and 2010, respectively. No income tax benefit was realized from stock option exercises during the years ended December 31, 2012, 2011 and 2010. The Company presents excess tax benefits from the exercise of stock options, if any, as financing cash flows rather than operating cash flows.

The total fair value of stock options vested during the years ended December 31, 2012, 2011, and 2010 was \$530,000, \$512,000, and \$1,218,000, respectively.

As of December 31, 2012, \$2,472,000 of total unrecognized compensation cost related to stock options is expected to be recognized over a weighted-average period of 2.83 years.

As of December 31, 2012, the Company had 117,000 options remaining in the Stock Option Plan available for grant.

#### ***(d) Warrants***

On February 6, 2007, the Company issued warrants to investors and a transaction advisor ("2007 Warrants"). The 2007 Warrants were exercisable immediately into an aggregate of 131,497 shares of the Company's common stock at \$46.25 per common share. These warrants expired during the first quarter of 2012 with no warrants having been exercised.

On March 18, 2010, the Company closed a registered direct financing in which warrants ("2010 Warrants") were issued to purchase 621,118 shares of its common stock. The exercise price of the 2010 Warrants is \$4.00 per share. The 2010 Warrants expired on September 18, 2011 with no warrants having been exercised.

On June 13, 2011, the Company issued 1,629,539 shares of its common stock as well as warrants ("Financing Warrants") to purchase 109,375 shares of its common stock in consideration of conversion and retirement of the Company's outstanding July and August 2009 debt obligations in the aggregate amount of \$2,149,000 with associated costs of \$41,000. The exercise price of the Financing Warrants is \$1.60 per common share representing the price per share equal to the closing bid price per share of the Company's common stock on the NASDAQ stock market on July 15, 2009.

On June 30, 2011, the Company closed a private placement financing in which 3,846,154 shares of common stock and warrants ("2011 Warrants") to purchase 3,846,154 shares of common stock for gross proceeds of approximately \$7,000,000 were issued. The investors purchased the shares and warrants for \$1.82 per unit (each unit consisting of one share and one warrant to purchase shares of common stock). The exercise price of the warrants is \$1.86 per share. The warrants are exercisable at any time from the date of issuance until June 30, 2016. The Company's estimated the fair value of the warrants at the date of issuance using the Black Scholes option model with a 101% volatility, 5.0 years expected life and a risk-free interest rate of 1.76%. The fair value of \$5,518,000 was classified as a current liability as the Company determined that these warrants do not meet the criteria for classification as equity. During 2012, 1,750,469 warrants were exercised for gross proceeds of \$3,256,000.

The Company accounts for the 2011 Warrants in accordance with US GAAP guidance applicable to derivative instruments. The Company determined that the 2011 Warrants do not meet the criteria for classification as equity. Accordingly, the Company classified the 2011 Warrants as current liabilities at December 31, 2012.

The Company initially allocated the total proceeds received, pursuant to the Securities Purchase Agreement, to the shares of common stock and warrants issued based on their relative fair values. This resulted in an allocation of \$3,012,000 of proceeds to warrant liability. Since under the derivative guidance the Company is required to record the derivatives at fair value, the Company therefore estimated the fair value of the warrants on the issuance date to be \$5,518,000, and recorded the increase to the warrant liability of \$2,506,000 as a charge other expense in its consolidated statements of operations as of June 30, 2011. Transaction costs associated with the issuance of the warrants of \$303,000 were immediately expensed and included as warrant issuance costs in the Company's consolidated statements of operations.

The estimated fair value of the 2011 Warrants at December 31, 2012 was determined using the Black-Scholes option-pricing model with the following weighted average assumptions:

Volatility.....	84%
Expected life of Warrants (years).....	3.50%
Risk-free interest rate.....	0.45%
Dividend yield.....	0%

The fair value of the 2011 warrants is highly sensitive to the changes in the Company's stock price and stock price volatility.

During the year ended December 31, 2012 certain holders of 2011 Warrants exercised 1,750,469 warrants. The Company received \$3,256,000 in proceeds from these exercises. The Company is required to record the outstanding warrants at fair value at the time of exercise, before moving the fair value into additional paid-in capital, resulting in an adjustment to the warrant obligations, with any gain or loss recorded in earnings of the applicable reporting period. The Company, therefore, estimated the fair value of the exercised 2011 Warrants at their respective exercise dates to be \$4,014,000, an increase of \$2,668,000 from the previous value at December 31, 2011 of \$1,346,000. The fair value was determined using the Black Scholes Merton option model with the following weighted average assumptions for volatility of 97%, 4.3 years expected life and a risk free rate of 0.85%. This increase was recorded as an expense in other income (expense) in the consolidated statement of operations and comprehensive income for the year ended December 31, 2012. There were no similar warrant exercises for the years ended December 31, 2011 and 2010.

The Company is also required to record the outstanding warrants at fair value at the end of each reporting period, resulting in an adjustment to the warrant obligations, with any gain or loss recorded in earnings of the applicable reporting period. The Company, therefore, estimated the fair value of the remaining warrants as of December 31, 2012 to be \$6,239,000, an increase of \$3,282,000 from the previous value at December 31, 2011. This amount was recorded as a charge to other income (expense) in the consolidated statement of operations and comprehensive income for the year ended December 31, 2012.

On June 13, 2011, in connection with the conversion of the notes payable and accrued interest (see Note 6), the Company issued warrants with a life of five years to purchase 109,375 shares of common stock. The exercise price of these warrants is \$1.60 per common share representing the price per share equal to the closing bid price per share of the Company's common stock on the NASDAQ stock market on July 15, 2009. The Company recorded \$163,000 representing the fair value of the warrants, calculated using the Black-



Scholes value model, at the date of the Financing in additional paid-in capital. The value of the warrants was accreted over the term of the Notes until their conversion in June 2011. During the year ended December 31, 2012 certain holders of these warrants exercised 22,500 warrants, with \$6,000 in proceeds received from these exercised warrants. As the estimated fair value of these warrants had been previously accreted over the term on the related Notes, no further accounting of these warrants is required. There were no similar warrant exercises for the years ended December 31, 2011 and 2010.

The following table provides activity for the Warrants issued and outstanding during the three years ended December 31, 2012 (in thousands, except weighted average exercise prices):

	Number of warrants outstanding	Weighted average exercise price
Outstanding, December 31, 2010 .....	753	\$ 11.38
Granted .....	3,955	1.85
Expired .....	<u>(621)</u>	<u>4.00</u>
Outstanding, December 31, 2011 .....	4,087	3.28
Exercised .....	(1,773)	1.86
Expired .....	<u>(131)</u>	<u>46.25</u>
<b>Outstanding, December 31, 2012.....</b>	<b><u>2,183</u></b>	<b><u>\$ 1.85</u></b>

## 11. CONSOLIDATED STATEMENTS OF CASH FLOWS

The net change in working capital and non-current asset balances related to operations consists of the following (*in thousands*):

	Years ended December 31,		
	2012	2011	2010
Accounts receivable.....	\$ (557)	\$ (5)	\$ (163)
Due from related parties .....	(11)	126	(130)
Inventory.....	(965)	(343)	(359)
Prepaid expenses .....	(197)	132	16
Other current assets .....	(25)	(20)	17
Other non-current assets .....	(27)	—	100
Accounts payable.....	849	(135)	(95)
Accrued liabilities.....	146	374	347
Deferred revenue .....	—	(128)	(23)
Due to stockholders .....	—	—	(10)
	<u>\$ (787)</u>	<u>\$ 1</u>	<u>\$ (300)</u>

The following table lists the non-cash transactions and additional cash flow information (*in thousands*):

	Years ended December 31,		
	2012	2011	2010
Warrant issued in registered direct financing .....	—	3,012	737
Common stock issued in consideration of management bonuses .....	1,182	—	—
Common stock issued in consideration of notes payable and accrued interest conversion .....	—	2,107	—
Common stock issued to Marchant Securities for services provided in the PIPE and bridge loan transactions.....	<u>—</u>	<u>—</u>	<u>155</u>

There were no interest or income taxes paid for the years ended December 31, 2012, 2011 & 2010.

### Employee Retirement Plan

The Company has a 401(k) retirement plan under which all full-time employees may contribute up to 100% of their annual salary, within IRS limits. The Company has not made any contributions to these retirement plan in the years ended December 31, 2012, 2011 and 2010.

### 12. QUARTERLY FINANCIAL DATA (UNAUDITED)

The following tables in the opinion of management, reflect all adjustments, consisting of normal recurring adjustments necessary for the fair presentation of results for the periods presented (in thousands, except per share data):

	Fiscal 2012 Quarter Ended (\$ 000's)			
	March 31	June 30	September 30	December 31
Revenue (i) .....	\$ 422	\$ 716	\$ 1,211	\$ 1,610
Gross profit (i) .....	91	375	519	680
Loss from operations (i) .....	(2,503)	(2,533)	(3,673)	(3,324)
Net loss (i) .....	\$ (9,099)	\$ (1,974)	\$ (4,587)	\$ (3,652)
Weighted average number of shares outstanding basic (i) .....	20,673	24,919	27,703	28,607
Net loss per common share basic (i) .....	\$ (0.44)	\$ (0.08)	\$ (0.17)	\$ (0.13)
Weighted average number of shares outstanding diluted .....	20,673	26,042	27,703	28,607
Net loss per common share diluted (i) .....	\$ (0.44)	\$ (0.10)	\$ (0.17)	\$ (0.13)

	Fiscal 2011 Quarter Ended (\$ 000's)			
	March 31	June 30	September 30	December 31
Revenue (i) .....	\$ 824	\$ 468	\$ 333	\$ 499
Gross profit (i) .....	412	192	(196)	90
Loss from operations (i) .....	(1,488)	(1,712)	(2,137)	(2,721)
Net loss (i) .....	\$ (1,667)	\$ (4,806)	\$ 1,137	\$ (3,472)
Weighted average number of shares outstanding basic and diluted (i) .....	14,775	15,282	20,778	20,415
Net loss per common share basic and diluted (i) .....	\$ (0.11)	\$ (0.31)	\$ 0.05	\$ (0.17)

(i) Net loss per share basic and diluted are computed independently for the quarters presented. Therefore, the sum of the quarterly per share information may not be equal to the annual per share information. Also totals may not add to the financials statements due to rounding.

**ITEM 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.**

Not applicable.

**ITEM 9A. Controls and Procedures.**

*Evaluation of Disclosure Controls and Procedures*

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow timely decisions regarding required disclosure. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefit of controls must be considered relative to their costs. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management necessarily is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As of the end of the period covered by the report, we carried out an evaluation, under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)). Based on that evaluation, our chief executive officer and chief financial officer concluded that, as at December 31, 2012 our disclosure controls and procedures were effective at the reasonable assurance level.

**MANAGEMENT'S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Because of its inherent limitations, internal control over financial reporting may not prevent or detect all misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

We conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in *Internal Control—Integrated Framework*, our management concluded that our internal control over financial reporting was effective as of December 31, 2012.

This annual report does not include an attestation report of the Company's independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's independent registered public accounting firm pursuant to the rules of the SEC that permit the Company to provide only a management's report in this report.

There has been no change in our internal control over financial reporting that occurred during the most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**ITEM 9B. Other Information.**

None.

### **PART III**

***ITEM 10. Directors, Executive Officers and Corporate Governance.***

The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

***ITEM 11. Executive Compensation.***

The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

***ITEM 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.***

The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

***ITEM 13. Certain Relationships and Related Transactions, and Director Independence.***

The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

***ITEM 14. Principal Accountant Fees and Services.***

The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

## PART IV

### ITEM 15. Exhibits and Financial Statement Schedules.

(a) The following documents are filed as part of the report:

(1) Financial Statements included in PART II of this report:

<b>Included in PART II of this report:</b>	<u>Page</u>
Report of Independent Registered Public Accounting Firm	38
Consolidated Balance Sheets as of December 31, 2012 and December 31, 2011	39
Consolidated Statements of Operations and Comprehensive loss for the three years ended December 31, 2012	40
Consolidated Statements of Stockholders' Equity for the three years ended December 31, 2012	41
Consolidated Statements of Cash Flows for the three years ended December 31, 2012	42
Notes to Consolidated Financial Statements	43

(2) Financial Statement Schedules:

#### SCHEDULE II – VALUATION AND QUALIFYING ACCOUNTS

	<u>Balance at beginning of period</u>	<u>Provision</u>	<u>Write-off and recoveries</u>	<u>Balance at end of period</u>
<i>(in thousands)</i>				
Fiscal 2010				
Bad debt reserves	\$ 7	\$ 39	\$ (33)	\$ 13
Product warranties	9	55	(13)	51
Fiscal 2011				
Bad debt reserves	13	32	(3)	42
Product warranties	51	56	(71)	36
Fiscal 2012				
Bad debt reserves	42	10	(16)	36
Product warranties	\$ 36	\$ 196	\$ (125)	\$ 107

(3) List of exhibits required by Item 601 of Regulation S-K. See part (b) below.

(b) Exhibits: The following exhibits are filed as a part of this report:

All other financial statement schedules have been omitted because they are not applicable, not required or the information required is shown in the financial statements or the notes thereto.

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Incorporated by Reference</u>
2.1	Form of Plan of Reorganization.	Exhibit 2.1 to the Registrant's Registration Statement on Form S-1/A No. 4, filed with the Commission on December 6, 2004 (file no. 333-118024)
3.1	Restated Certificate of Incorporation of OccuLogix, Inc., filed with the Secretary of State of the State of Delaware on October 7, 2008.	Exhibit 3.3 to the Registrant's Current Report on Form 8-K filed with the Commission on October 9, 2008 (file no. 000-51030)

<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Incorporated by Reference</b>
3.2	Amended and Restated By-Laws of the Registrant as currently in effect.	Exhibit 3.4 to the Registrant's Registration Statement on Form S-1/A No. 3, filed with the Commission on November 16, 2004 (file no. 333-118024)
3.3	Certificate of Amendment of OccuLogix, Inc., filed with the Secretary of State of the State of Delaware on October 7, 2008.	Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed with the Commission on October 9, 2008 (file no. 000-51030)
3.4	Certificate of Amendment of OccuLogix, Inc., filed with the Secretary of State of the State of Delaware on October 1, 2008.	Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed with the Commission on October 1, 2008 (file no. 000-51030)
3.5	Certificate of Amendment of OccuLogix, Inc., filed with the Secretary of State of the State of Delaware on May 18, 2010.	Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed with the Commission on May 19, 2010 (file no. 000-51030)
4.1	Form of Common Stock Purchase Warrant Agreement	Exhibit A to the Registrant's free writing prospectus filed with the Commission on March 15, 2010 (file no. 333-157269)
4.2	Form of Common Stock Purchase Warrant Agreement	Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed with the Commission on July 16, 2009 (file no. 000-51030)
10.1	License Agreement between TearLab, Inc. and The Regents of the University of California dated March 12, 2003.	Exhibit 10.48 to the Registrant's Annual Report on Form 10-K/A, filed with the Commission on March 29, 2007 (file no. 000-51030) (Portions of this exhibit have been omitted pursuant to a request for confidential treatment.)
10.2	Amendment No. 1, dated June 9, 2003, to the License Agreement between TearLab, Inc. and The Regents of the University of California dated March 12, 2003.	Exhibit 10.49 to the Registrant's Annual Report on Form 10-K/A, filed with the Commission on March 29, 2007 (file no. 000-51030)
10.3	Amendment No. 2, dated September 5, 2005, to the License Agreement between TearLab, Inc. and The Regents of the University of California dated March 12, 2003.	Exhibit 10.50 to the Registrant's Annual Report on Form 10-K/A, filed with the Commission on March 29, 2007 (file no. 000-51030) (Portions of this exhibit have been omitted pursuant to a request for confidential treatment.)
10.4	Amendment No. 3, dated July 7, 2006, to the License Agreement between TearLab, Inc. and The Regents of the University of California dated March 12, 2003.	Exhibit 10.51 to the Registrant's Annual Report on Form 10-K/A, filed with the Commission on March 29, 2007 (file no. 000-51030)
10.5	Amendment No. 4, dated October 9, 2006, to the License Agreement between TearLab, Inc. and The Regents of the University of California dated March 12, 2003.	Exhibit 10.52 to the Registrant's Annual Report on Form 10-K/A, filed with the Commission on March 29, 2007 (file no. 000-51030)
10.6	Terms of Business, dated February 5, 2007, between Invetech Pty Ltd. and TearLab, Inc.	Exhibit 10.30 to the Registrant's Annual Report on Form 10-K, filed with the Commission on March 17, 2008 (file no. 000-51030)
10.7	Amendment No. 5, dated June 29, 2007, to the License Agreement between TearLab, Inc. and The Regents of the University of California dated March 12, 2003. (Portions of this exhibit have been omitted pursuant to a request for confidential treatment.)	Exhibit 10.31 to the Registrant's Annual Report on Form 10-K, filed with the Commission on March 17, 2008 (file no. 000-51030)

<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Incorporated by Reference</b>
10.8	2002 Stock Option Plan, as amended and restated on June 24, 2010.	Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the Commission on July 23, 2010 (file no. 000-51030)
10.9	Loan Agreement, dated as of February 19, 2008, by and among the Registrant, the Lenders named therein and Marchant Securities Inc.	Exhibit 10.50 to the Registrant's Annual Report on Form 10-K, filed with the Commission on March 17, 2008 (file no. 000-51030)
10.10	Share Pledge Agreement, dated as of February 19, 2008, by the Registrant in favor of Marchant Securities Inc., as collateral agent.	Exhibit 10.51 to the Registrant's Annual Report on Form 10-K, filed with the Commission on March 17, 2008 (file no. 000-51030)
10.11	Employment Agreement, dated as of February 25, 2008, between the Registrant and William G. Dumencu.	Exhibit 10.52 to the Registrant's Annual Report on Form 10-K, filed with the Commission on March 17, 2008 (file no. 000-51030)
10.12	Amending Agreement by and among OccuLogix, Inc., Marchant Securities Inc. and the investor party thereto.	Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the Commission on July 28, 2008 (file no. 000-51030)
10.13	Letter Agreement, dated January 8, 2010, amending the Capital Advisory Agreement with Greybrook Capital Inc.	Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the Commission on January 11, 2010 (file no. 000-51030)
10.14	Placement Agency Agreement, dated as of March 14, 2010, by and between the Company and Rodman & Renshaw, LLC.	Exhibit 99.1 to the Registrant's Current Report on Form 8-K filed with the Commission on March 15, 2010 (file no. 000-51030)
10.15	Securities Purchase Agreement, dated as of March 14, 2010, by and between the Company and certain investors.	Registrant's free writing prospectus filed with the Commission on March 15, 2010 (file no. 333-157269)
10.16	Distribution Agreement, dated as of August 20, 2009, by and between the Company and Science with Vision, a Canadian corporation.	Exhibit 99.5 to the Registrant's Current Report on Form 8-K filed with the Commission on March 15, 2010 (file no. 000-51030)
10.17	Capital Advisory Agreement with Greybrook Capital Inc., dated November 3, 2009	Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the Commission on November 3, 2009 (file no. 000-51030)
10.18	Form of Director and Affiliate Letter Agreement.	Exhibit 10.5 to the Registrant's Current Report on Form 8-K filed with the Commission on July 16, 2009 (file no. 000-51030)
10.19	# Agency Agreement, dated February 22, 2012, by and between TearLab Corporation and Dr. Graves.	Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the Commission on February 27, 2012 (file no. 000-51030)
10.20	Deed and Amendment, dated December 22, 2011, to Manufacturing and Development Agreement by and between TearLab Research, Inc. and MiniFAB AB (Aust) Pty Ltd. Dated August 1, 2011 (Portions of this exhibit have been omitted pursuant to a request for confidential treatment.).	Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the Commission on December 29, 2011 (file no. 000-51030)
10.21	Manufacturing and Development Agreement by and between TearLab Research, Inc. and MiniFAB (Aust) Pty Ltd, dated August 1, 2011. (Portions of this exhibit have been omitted pursuant to a request for confidential treatment.)	Exhibit 10.5 to the Registrant's Current Report on Form 8-K filed with the Commission on August 25, 2011 (file no. 000-51030)
14.1	Code of Conduct of the Registrant	
14.2	Complaint and Reporting Procedures of the Registrant.	Exhibit 14.2 to the Registrant's Quarterly Report on Form 10-Q, filed with the Commission on August 9, 2005 (file no. 000-51030)



Exhibit Number	Exhibit Description	Incorporated by Reference
21.1	Subsidiaries of Registrant.	Exhibit 21.1 to the Registrant's Registration Statement on Form S-1, filed with the Commission on July 28, 2011 (file no. 333-175861)
23.1	Consent of Independent Registered Public Accounting Firm.	
24.1	Power of Attorney (included on signature page).	
31.1	CEO's Certification required by Rule 13A-14(a) of the Securities Exchange Act of 1934.	
31.2	CFO's Certification required by Rule 13A-14(a) of the Securities Exchange Act of 1934.	
32.1	CEO's Certification of periodic financial reports pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, U.S.C. Section 1350.	
32.2	CFO's Certification of periodic financial reports pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, U.S.C. Section 1350.	
101.INS*	XBRL Instance	
101.SCH*	XBRL Taxonomy Schema	
101.CAL*	XBRL Taxonomy Extension Calculation	
101.DEF*	XBRL Taxonomy Extension Definition	
101.LAB*	XBRL Taxonomy Extension Labels	
101.PRE*	XBRL Taxonomy Extension Presentation	

\* \* \*

**#Management compensatory plan, contract or arrangement**

- XBRL information is furnished and not filed or a part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections.

Copies of the exhibits filed with this Annual Report on Form 10-K or incorporated by reference herein do not accompany copies hereof for distribution to stockholders of the Registrant. The Registrant will furnish a copy of any of such exhibits to any stockholder requesting the same for a nominal charge to cover duplicating costs.

### **POWER OF ATTORNEY**

The registrant and each person whose signature appears below hereby appoint Elias Vamvakas and William G. Dumencu as attorney-in-fact with full power of substitution, severally, to execute in the name and on behalf of the registrant and each such person, individually and in each capacity stated below, one or more amendments to this Annual Report on Form 10-K, which amendments may make such changes in this Annual Report as the attorney-in-fact acting in the premises deems appropriate and to file any such amendments to this Annual Report on Form 10-K with the Securities and Exchange Commission.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned thereunto duly authorized.

Dated: March 25, 2013

TearLab Corp.

By: /s/ Elias Vamvakas  
Elias Vamvakas  
Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Dated: March 25, 2013

By: /s/ Elias Vamvakas  
Elias Vamvakas  
Chief Executive Officer and  
Chairman of Board of Directors

Dated: March 25, 2013

By: /s/ William G. Dumencu  
William G. Dumencu  
Chief Financial Officer and Treasurer

Dated: March 25, 2013

By: /s/ Anthony Altig  
Anthony Altig  
Director

Dated: March 25, 2013

By: /s/ Thomas N. Davidson, Jr.  
Thomas N. Davidson, Jr.  
Director

Dated: March 25, 2013

By: /s/ Adrienne L. Graves  
Adrienne L. Graves  
Director

Dated: March 25, 2013

By: /s/ Richard L. Lindstrom, M.D.  
Richard L. Lindstrom, M.D.  
Director

Dated: March 25, 2013

By: /s/ Donald Rindell  
Donald Rindell  
Director

Dated: March 25, 2013

By: /s/ Paul Karpecki  
Paul Karpecki  
Director

Dated: March 25, 2013

By: /s/ Brock Wright  
Brock Wright  
Director

**Consent of Independent Registered Public Accounting Firm**

We consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-124505, 333-155163 and 333-181949) and related Prospectus' of our report dated March 25, 2013, with respect to the consolidated financial statements and schedule of TearLab Corp. included in this Annual Report (Form 10-K) for the year ended December 31, 2012.

/s/ Ernst & Young LLP

San Diego, California  
March 25, 2013

CERTIFICATION PURSUANT TO RULE 13A-14 OR 15D-14 OF  
THE SECURITIES EXCHANGE ACT OF 1934,  
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Elias Vamvakas, certify that:

1. I have reviewed this Annual Report on Form 10-K of TearLab Corp.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under the Company's supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under the Company's supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report the Company's conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on the Company's most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 25, 2013

/s/ Elias Vamvakas  
Elias Vamvakas  
Chief Executive Officer

CERTIFICATION PURSUANT TO RULE 13A-14 OR 15D-14 OF  
THE SECURITIES EXCHANGE ACT OF 1934,  
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, William G. Dumencu, certify that:

1. I have reviewed this Annual Report on Form 10-K of TearLab Corp.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under the Company's supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under the Company's supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report the Company's conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on the Company's most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 25, 2013

/s/ William G. Dumencu  
William G. Dumencu  
Chief Financial Officer and Treasurer

**CERTIFICATION PURSUANT TO  
18 U.S.C SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report on Form 10-K of TearLab Corp. (the "Company") for the year ended December 31, 2012, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Elias Vamvakas, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

By: /s/ Elias Vamvakas  
Elias Vamvakas  
Chief Executive Officer

Dated: March 25, 2013

CERTIFICATION PURSUANT TO  
18 U.S.C SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of TearLab Corp. (the "Company") for the year ended December 31, 2012, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, William G. Dumencu, Chief Financial Officer and Treasurer of the Company, certify, pursuant to 18 U.S.C. section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

By: /s/ William G. Dumencu  
William G. Dumencu  
Chief Financial Officer and Treasurer

Dated: March 25, 2013





## STOCKHOLDER INFORMATION

Corporate Office  
7360 Carroll Road, Suite 200  
San Diego, California 92121  
T: 858.455.6006 F: 858.812.0540

International Corporate Office  
5090 Explorer Drive, Suite 203  
Mississauga, Ontario L4W 4T9  
T: 858.455.6006

## TRANSFER AGENT AND STOCKHOLDER RECORDS

*Stockholders requiring information  
or assistance regarding individual stock records  
or stock certificates should contact the  
appropriate Transfer Agent:*

Transfer Agent (U.S.):  
Computershare  
P.O. Box 43006  
Providence, RI 02940-3006  
T: 888.667.7671  
[www.computershare.com/investor](http://www.computershare.com/investor)

Co-agent (Canada):  
Equity Financial Trust Company  
T: 416.361.0152  
[www.equityfinancialtrust.com](http://www.equityfinancialtrust.com)

Independent Auditors: Ernst & Young LLP

CORPORATE OFFICE

7360 Carroll Road, Suite 200

San Diego, California 92121

T: 858.455.6006

F: 858.812.0540

INTERNATIONAL CORPORATE OFFICE

5090 Explorer Drive, Suite 203

Mississauga, Ontario L4W 4T9

T: 858.455.6006

[www.TearLab.com](http://www.TearLab.com)



NASDAQ: TEAR · TSX: TLB