EDISON

SQI Diagnostics

Initiation of coverage

Looking towards deal execution

Healthcare equipment & services

9 January 2014

Price	**C$0.53**
Market cap	**C$24m**
	C$1.05/US$
Net cash (C$m) 31 Dec 2013 (estimate)	0.5
Shares in issue	45.0m
Free float	84%
Code	SQD
Primary exchange	TSX-Venture
Secondary exchange	N/A

SQI designs and develops highly efficient and accurate immunological diagnostics. There are two main customers for these tests, pharma companies/CROs to analyse clinical trial data, and centralised diagnostics laboratories. Ongoing collaborations with Bristol-Myers Squibb (BMS) and Isis Pharmaceuticals, with multiple discussions in the pipeline, underscore the pharma customer opportunity. Delivering on existing contracts and securing new customers are key to SQI's investment case. We value SQI at C$70m, or C$1.55/share, but a ~C$4m funding requirement is an overhang.

Year end	Revenue (C$m)	PBT* (C$m)	EPS* (C$)	DPS (C$)	P/E (x)	Yield (%)
09/12	0.0	(6.2)	(0.17)	0.0	N/A	N/A
09/13	0.0	(6.1)	(0.15)	0.0	N/A	N/A
09/14e	1.6	(4.9)	(0.11)	0.0	N/A	N/A
09/15e	11.4	1.2	0.03	0.0	17.7	N/A

Note: *PBT and EPS are normalised (excl. amortisation/exceptional). Revenues are risk adjusted.

Demand for greater efficiency and accuracy

SQI's Ig_PLEX technology is able to determine the fine detail of any immune response, particularly anti-drug antibodies (ADA), cytokines and antibodies associated with autoimmune diseases. A comprehensive diagnostic data set is of increasing importance to the FDA in its review of new drug applications, which is driving demand for more efficient (time/cost saving) and accurate diagnostic tools.

Focus on pharma customers

The BMS collaboration has provided important validation of SQI's technology, with data showing that Ig_PLEX is twice as sensitive as current single-well assays and eight times more sensitive than its closest multiplex competitor. The Isis deal to develop a multiplexed assay, and further agreements with two (undisclosed) large pharma customers, highlight the commercial potential. SQI is primarily focused on delivering on its existing contracts and converting the sales pipeline (such as a scoped project with a biotech company) into fresh contracts.

Significant IVD opportunity

SQI is also developing Ig_PLEX assays for autoimmune disease testing, initially focused on three indications: celiac disease, vasculitis and lupus. Celiac disease is a big screening market, and Canadian approval in Q114 and FDA 510(k) approval by mid-2014 could be secured for SQI's multiplex test. This will be sold to large central laboratories in the US and Canada. Autoimmune tests for vasculitis and lupus are expected to follow in 2014 and 2015.

Valuation: C$70m, or C$1.55 per share

We value SQI at C$70m, or C$1.55 per share, based on a five-year, risk-adjusted, sum-of-the-parts DCF valuation. This includes a terminal value component (0.5% on 2018 free cash flow) and applies a 12.5% discount rate. This is not a price target but a fair value for the stock today. This is driven by the pharma customer business, and assumes consistent and timely execution of existing and new contracts. SQI has a ~C$4m funding requirement but profitability could be achieved by end-2015.

Share price performance

%	1m	3m	12m
Abs	(11.7)	(27.4)	23.3
Rel (local)	(13.8)	(32.3)	13.2
52-week high/low	C$1.10	C$0.33	

Business description

SQI Diagnostics is a Canadian diagnostics company. SQI develops and sells multiplexed research diagnostics to pharmaceutical companies to support clinical research, and *in vitro* diagnostic tests to centralised diagnostic laboratories for diagnosing autoimmune diseases, such as celiac, lupus and vasculitis.

Next events

Financing update	Q114
Pharma customer deals	2014
Canada approval for celiac test	Q114

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Edison profile page

Investment summary

Company description: A quick diagnosis

SQI Diagnostics was founded in 1999, listed on the TSX Venture Exchange in 2007, is based in Toronto, Canada, and has 35 employees. SQI designs and develops highly efficient and accurate multiplexed immunological diagnostics, based on its Ig_PLEX technology where several substances can be analysed at a time. SQI has two key markets: pharmaceutical companies that can use SQI's customised research diagnostic tests to analyse clinical trial data; and centralised diagnostics laboratories that conduct high-throughput screening assays and could adopt SQI's planned menu of *in vitro* diagnostic (IVD) tests, particularly for autoimmune disorders. Bristol-Myers Squibb and Isis Pharmaceuticals are existing pharmaceutical customers and SQI hopes to convert pipeline leads into new customers over the coming months. Its IVD business should start to take shape over the next two years, with regulatory (FDA and Canada) approvals for celiac, vasculitis and lupus tests, which could then be sold to diagnostic laboratories.

Valuation: C$70m, or C$1.55 per share

We value SQI at C$70m, or C$1.55 per share, based on a five-year (2014-18), risk-adjusted, sum-of-the-parts DCF valuation. This includes a terminal value component (0.5% on 2018 free cash flow) and applies a standard 12.5% discount rate. This is not a price target but a fair value for the stock today. Approximately two-thirds of value is attributed to the pharma customer business, which assumes consistent and timely execution of existing and new contracts. Upside would come from a more rapid uptake of assays and machines from pharma customers and centralised laboratories than we currently model. The risk-adjustment applied to cash flows from each business unit relates to commercial/competitive risk (ie the ability to secure new customers in a competitive field), as opposed to technical risk associated with gaining regulatory approvals.

Sensitivities: Low technical, higher commercial risk

The publication by Algorithme and BMS of validation data on Ig_PLEX, and the existing deals with Isis Pharmaceuticals and three further pharma customers, reduces the investor risk profile as they provide independent validation of SQI's technology and its utility. Technical risk appears moderate. Conversely, at this stage, with modest revenues to date, there is reasonable commercial risk in SQI achieving the near-term sales targets we have modelled. The diagnostics field is highly competitive, with a number of large companies able to apply significant resources to promotion and commercialisation activities. The challenge for SQI will be in communicating and convincing customers of the improved accuracy and efficiency of its Ig_PLEX technology. We have assumed a consistent stream of new customers and a timely execution on these contracts, such that any significant delays in uptake could have a negative impact on our valuation. SQI's pipeline of both new customers and new assays looks promising, so delivery on these fronts, particularly over 2014 and 2015, could significantly improve valuations and sentiment.

Financials: Funding requirement, but FY15 profitability target

We estimate SQI ended fiscal Q114 (31 December 2013) with C$0.5m in cash (vs $1.4m at 30 September 2013). This highlights an imminent financing requirement, and we have assumed C$4m is raised in 2014, nominally attributed to long-term debt. SQI last raised funds in May 2013, realising C$3.5m (net) from the sale of 5.1m shares at C$0.75 and 5.1m warrants (exercisable at C$1.10, expire 1 May 2015). Revenues in FY13 were C$3,000 (vs C$12,000 in FY12). We model risk-adjusted revenues in fiscal FY14 and FY15 at C$1.6m and C$11.4m, respectively. Importantly, even on a risk-adjusted revenue basis, our model indicates that SQI could achieve profitability by the end of 2015.

Outlook: Defined by deal delivery

SQI is focused on selling its research diagnostic tools to pharmaceutical customers and developing its *in vitro* diagnostics business for commercialisation through centralised diagnostic laboratories in the US and Canada. Contracts with pharmaceutical companies involve an initial validation phase, but once this hurdle is cleared, the potential for SQI to establish an extensive and retained portfolio of business with a pharma company could be significant. For IVDs, developing a menu of approved assays for multiple diseases is the long-term goal, which could lead to a substantial business by selling these tests to >1,500 diagnostic laboratories in North America. Delivering on existing contracts and securing new customers (pharma companies and laboratories) is key to SQI's investment case; should our near-term forecasts be met, SQI could achieve profitability by the end of 2015.

A multiplexed approach

Multiplexing is running several diagnostic tests – two to 10 is common, many more are possible – in the same tube or well with one sample. The material and time needed are not much greater than is needed for one test in one well, instrument time is maximised and the labour required is minimised so productivity (tests per hour per dollar) improves. The alternative is running separate tests in different wells, which is the traditional ELISA method, also referred to as single-plexing.

Multiplexing is ideal where several related tests are required to make a confirmed diagnosis and when these are normally ordered or required as a standard set. Multiplexing has the following key features and advantages:

- Multiple tests can be conducted on a small patient sample.
- All tests are conducted in exactly the same way, eliminating the potential impact of different methods, timing or conditions on results.
- Control tests are more reliable because they are performed under the same conditions as the test sample (simultaneously and in the same well).
- It is more likely to determine the cause of disease or targets of drugs, as multiple potential markers can be assessed at once, rather than having to target specific ones.

SQI has selected immune conditions where the clinical outcome can have several manifestations due to the complexity and variability of the immune response. Examples include anti-drug antibody detection (ADA), isotyping, vaccine development and autoimmune conditions, like celiac disease. Potentially, the approach would also be suitable for allergy testing.

ADA, an immune response that neutralises a biological therapeutic, is common when a biological drug is repeatedly given, although techniques to reduce or eliminate this (such as totally human therapeutic antibodies) have been developed. The FDA set new standards to test for this in clinical development in 2009. These tests generate large numbers of blood samples since patients in a trial may have a blood sample taken when each dose of drug is administered. Regular testing will allow development of any response against the drug to be tracked as this may affect efficacy and safety.

Isotyping identifies the type of patient antibody binding to a target like a biological therapeutic and the FDA requires isotyping of any ADA response. The classes of antibody are IgG (found in the blood and tissues and used to target bacteria and foreign proteins), IgA (found in large quantities in the mucosa and intestine to defend against infection), IgE (normally in trace amounts and involved in allergy) and IgM (a large antibody complex produced in the first stages of fighting infection).

In ADA testing, the biological therapeutic will be present at some level in the patient's blood, which could interfere with the assay. A key differentiation is that SQI's tests are highly tolerant of free drug, with data from a BMS study showing Ig_PLEX to be >8x more robust than a competing product.

Spots vs beads

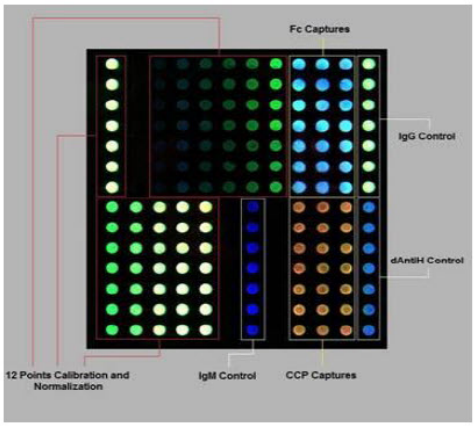
Multiplexed tests can be complex to develop because each read-out needs to co-exist within a similar range, and the chemistry and detection system need to minimise crosstalk between the tests. There appear to be two general multiplex approaches: beads and spots. Tests can be automated or purely manual and normally require dedicated instrumentation and software.

Bead-based tests are common in the multiplex space. Beads can be colour-coded, with each colour bead bound with a different test reagent, usually a particular substance or antibody. To multiplex the assays, the different beads are just mixed together. A sample is then added and the different beads pick out the different analytes. Detection usually uses fluorescent markers for sensitivity. To read the assay, a machine separates the beads and detects the colour of each bead to identify the assay type, while a second reader measures the signal on the bead to calculate the result.

Bead assays, in theory, can run many multiplexed assays in one test; the xMAP bead technology is a standard and claims potentially high multiplexing levels. Bead assays originated in DNA analysis where high plex rates are feasible, and have been adapted for proteins. Bio-Rad, which uses xMAP beads from Ilumina, claims that 50% of multiplex tests use its Bio-Plex system. However, bead assays have drawbacks, mainly accuracy as the number of multiplexed assays rises. If tests are qualitative or low plex numbers this is less of an issue, but higher volume quantification may be problematic due to cross-talk when multiple isotype assays are attempted.

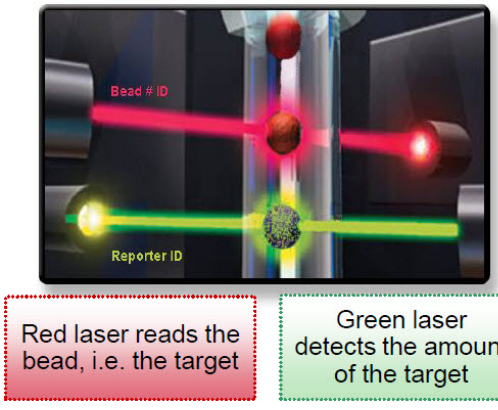
The other approach, as used by SQI in its Ig_PLEX range, is to print small spots of different proteins at precise locations within one well of an industry standard 96-well (12x8) array on a plate. Detection uses fluorescent dyes bound to reporter antibodies (as with SQI) or by electrochemiluminescence (ECL). Besides the SQI system, there are other multiplexed spot systems. For example, Genalyte's Maverick MT assay uses a linear slide format and the Meso Scale Discovery (MSD) and Quansys systems use 96 well plates with multiple spots. MSD appears to be widely used in pharmaceutical development as its bridging assay can be developed at the pre-clinical stage and used unchanged through Phase III. SQI's Ig_PLEX has a similar advantage, while also enabling sub-class isotyping, which bridging assays cannot detect. Other available systems require recalibration between preclinical and for clinical trials, meaning data are discontinuous. The general spot vs bead approach can be visualised in Exhibits 1 and 2.

Exhibit 1: Spot test (Ig_PLEX)



Source: SQI presentation (spots within one well)

Exhibit 2: Bead test (AtheNA Multi-Lyte)



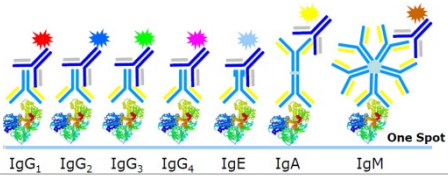
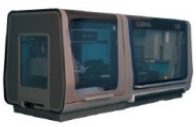
Source: SQI presentation

SQI's multiplexing advantage

As developed by SQI, miniscule spots of pure proteins are precisely printed onto a glass slide in 96 clusters. A perforated mask is then bonded to the plate to give 96 wells, each with 100-400 spots. To run the test, one patient sample is incubated per well. After washing and addition of detection

reagents, an instrument detects the signal on each spot. As the location and identity of each spot is known, in effect, each is a separate assay, so there is no identification step needed. SQI has different fluorescent labels that can be attached to different detection agents, usually antibodies. These are detected by illuminating the plate at different wavelengths of light. In practice six to 12 tests per well is adequate for most purposes but many more could be obtained; an 18 biomarker per well test is in development and more are possible. Crucially, this system allows the different types of antibodies (isotypes) produced by an immune response to be differentiated and measured. Isotyping is a critical, FDA-required aspect of current bio-pharmaceutical development. Multiplexing isotyping assays with greater accuracy and robustness to potential contaminants gives SQI an important competitive advantage. SQI's technology is summarised in Exhibit 3.

Exhibit 3: SQI Diagnostics technology

Feature	Comments
Spots	Proteins are printed onto glass plates in clusters of 96. This corresponds with standard 96-well (12x8) plates used for sample preparation by many laboratories. Each cluster in a well can comprise 100 to 400 spots.
Multiple proteins	Different types of protein or DNA are printed onto exact locations on the plate. This means there is no need for a separate identification step, as with bead based multiplex systems.
Standard format	Once printed, a plastic mask is glued onto the glass plate to form a reaction well for each cluster.
Running assays	One sample is added per well. As each type of spot is replicated between seven and 15 times in each well, there is no need to run duplicate samples. A standard ELISA needs duplicates samples, doubling the number of reactions required and the cost.
Multi-colour detection	SQI has fluorescent tags that can be attached to different reporter antibodies or proteins. These tags have been selected so that they do not have significant spectral overlap. Proteins are immobilised on the glass plate in a spot. Patient antibodies bind to this protein. The reporter antibodies bind to the different isotypes of patient antibody. 
Reading the plate	By illuminating the plate at three different light frequencies, the different coloured fluorescent tags light up. The signal from each spot is measured and compared to a calibration curve to give the amount of binding and the identities of the reporter antibodies. Each reporter may bind to each spot, but each is separately detected at the different frequencies.
Isotype detection	Typically, a clinical-stage customer may detect total IgG, IgA and IgM. Antibody subtypes will be measured in one or two different wells since total IgG/A cannot be run in the same well as specific subtype assays. Individual subtype assays have different calibration curves.
Key aspects	SQI optimises each assay to ensure that the density of antibodies on each spot is not too great as this could interfere with the accuracy of the assay. If the dilution range is too wide for some analytes, a separate well can be used. Different proteins have different properties so the production of these assays needs to be carefully optimised.
Equipment platforms	  

	SQiDworks	SQiDlite	SQiD-X
Throughput	1000+ results / hour	330+ results / hour	200+ results / hour
Size	Foot Print 36" x 66"	Bench Top 20" x 48"	Bench Top 18" x 24"
Target Customer	High Volume Ref Labs Top 1,000 NA / EU Labs	IVD, OEM, RUO (LDTs Non-IVD), Top 5,000 Labs	Research / Non-IVD
Hands-on Time for 1 Plate	15 minutes	15 minutes	45 minutes

Source: Edison Investment Research, SQI presentation

SQI has three machines to run its assays: SQiD-X, a semi-automated, multiplexed, bench-top machine, typically used by earlier stage, lower volume customers; SQiDlite, a fully-automated bench-top machine, which customers transition to from SQiD-X as volumes and complexity increase; and SQiDworks, a high-throughput, fully-automated machine, able to cope with the highest complexity of tests, delivering the greatest cost-savings to high-throughput customers.

Converting technology into sales

For all of Ig_PLEX's technical and commercial advantages, the challenge for SQI is to convert this into revenues. This could be achieved by proper positioning and selective targeting within two key markets: pharmaceutical companies and contract research organisations (CROs) (to analyse clinical trial data) and centralised diagnostic laboratories (to screen for multiple diseases, particularly autoimmune).

Sales to pharmaceutical companies/CROs

SQI refers to this business unit as 'Diagnostic Tools and Services (DTS)' and the company has shown through disclosed collaborations that it is highly skilled at optimising specific multiplex tests for pharmaceutical customers. Exhibit 4 discusses common test types.

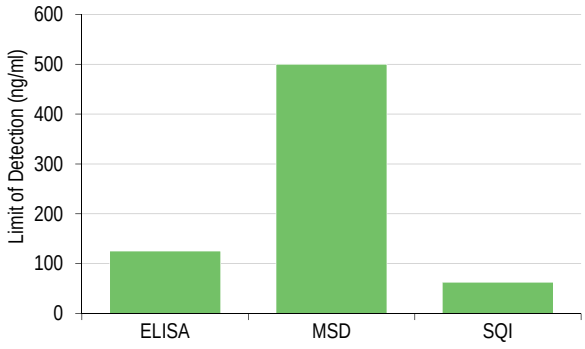
Exhibit 4: Pharmaceutical test types

Test for	Uses	Proteins spotted on plate	Detects
Anti-drug antibodies (ADA)	Any biological therapeutic, like an antibody, can potentially generate an immune response in the patient. The FDA requires these to be characterised.	Only the biological drug, so the plate is easy to develop but SQI also needs to optimise the detection system and isotype detection	Patient antibodies binding to the bio-therapeutic.
Biomarkers and cytokines	Used in many clinical trials to assess any immune inflammatory response, particularly with vaccines.	SQI has an 18-plex plate in development.	Quantification is critical to assess disease and treatment response.
Custom assays	Trials have many possible endpoints and parameters. Analysis of blood samples from large trials by single-plex ELISA could take months.	Generally 6-plex assays are required. Multiplexing speeds up data release to weeks or less.	As required but more complex assays are costly to develop and SQI can charge a higher price per plate.

Source: Edison Investment Research

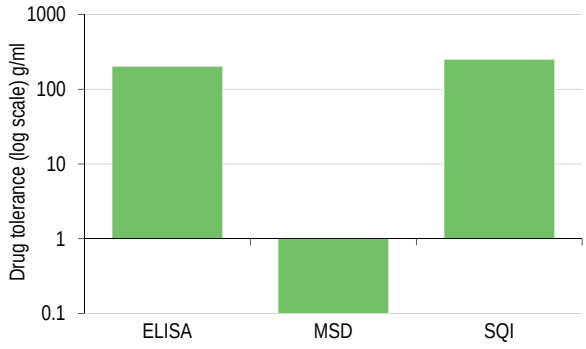
SQI appears to have strong technical advantages as shown by the validation study[1] conducted by BMS. In a model system, the SQI assay (using the SQiD-X machine) was 50% more sensitive in detecting ADA than ELISA and eight times better than Meso Scale Discovery bridging assays, at greater dilution (Exhibit 5). It was also more tolerant of free drug levels (Exhibit 6). This could be a major sales advantage since bridging assays are unreliable in the presence of free drug. SQI and Algorithme Pharma (Algorithme) have also done a proof-of-concept assay showing excellent data.[2]

Exhibit 5: Defection sensitivity (low = more sensitive)



Source: BMS 8 October 2013

Exhibit 6: Tolerance of free drug (high = more tolerant)



Source: BMS 8 October 2013

SQI made significant progress in 2013 in securing new customers, major pharmaceutical companies, for its DTS business. The current status of its contracts with these customers is displayed in Exhibit 7. For confidentiality reasons, these customers often cannot be named, which is fairly typical of contracts in the diagnostics sector.

1 Isotyping Therapeutic Protein Immunogenicity in an Automated Multiplexed Assay. October 2013
2 A Novel Approach for Multiplexed Detection, Isotyping and Quantitation of IgG, IgA and IgM anti PF4/Heparin Antibodies using SQI Diagnostics' Ig_PLEX Technology. July 2013.

Exhibit 7: Current status of pharma customer contracts

Product	Stage of development					
	Candidate panel	Proof-of-concept	Assay development	Automation	Validation	Ready to commercialise
Cytokines 8 PLEX						
Heparin Immunogenicity ('HIT') Assay						
Global Pharma 1						
Global Pharma 2						
Isis Pharmaceuticals						
Global Pharma 3						

Source: Company documents, Edison Investment Research

For each of these contracts, we summarise some of the key features:

- **Cytokines 8 PLEX** – Initially developed on SQiD-X; successful evaluation (in Q114 for Global Pharma 2) would lead to sale of test kits and SQiDlite machines.
- **Heparin Immunogenicity ('HIT') Assay** – Collaboration with Algorithme Pharma (January 2013); proof-of-concept complete; Algorithme started marketing it as a 'shelf-ready' multiplexed assay.
- **Global Pharma 1** – Developing a proof-of-concept ADA assay to detect/quantify immune response to a new class of drug. Customer demonstrated greater sensitivity and free-drug tolerance with Ig_PLEX (with high reproducibility) and SQI believes the customer will adopt SQI technology in future clinical studies.
- **Global Pharma 2** – Developing a 21-plex ADA assay for a development-stage biologic. SQI believes the customer will proceed to order test kits on the SQiD-X platform.
- **Isis Pharmaceuticals** – Development agreement with Isis to design a multiplexed ADA assay for an Isis pipeline candidate; a successful test could be adopted by Isis's CRO, which may then be applicable to other Isis pipeline candidates.
- **Global Pharma 3** – Commercial agreement to develop a 6-plex ADA assay to measure immunogenic responses against one pipeline candidate; assay may be adopted by the customer's CRO. Customer will pay for development work and consumables used.

Sales development

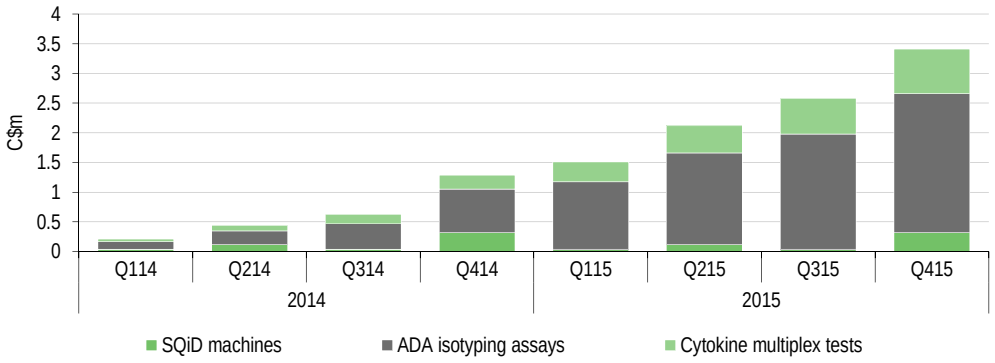
A typical contract with a pharmaceutical customer involves test design, development and validation services, resulting in customised multiplex tests. This leads to the manufacture and sale of these custom kits for use in the customer's pre-clinical and clinical drug trials. These tests are often contracted out by the pharma company to a CRO, so SQI's customer could also become the CRO, which would help to strengthen the overall relationship and provide further opportunities.

For revenue forecasting, it is been assumed SQI secures one new client per quarter from Q114. Each customer will initially need to buy one to three SQiD platforms, mainly SQiD-X (~C$40,000) and SQiDlite (~C$80,000) systems to run the tests. SQiD-X is typically required for the initial proof-of-concept work, with SQiDlite used for full automation. For modelling purposes we have assumed that in any 12-month period, four SQiD-X, two SQiDlite and one SQiDworks (~C$200,000) machines are sold. SQI then sells customised assays as continuing projects require them, and as new projects start up. The amount of work, and revenue received, from each customer will gradually increase, from $200,000 in the first six months, to C$1.6m per year on a retained basis. Our assumption is that by Q415, SQI will have eight pharma customers, each generating different revenue levels depending on the maturity of those contracts.

Once SQiDlite systems are installed, SQI also plans to sell biomarker (including cytokine) tests. It has an 8-plex cytokine assay running, with a 10-plex available in 2014 and a quantitative 10-plex offered in 2015. Like the ADA isotyping project work, we assume each customer will gradually scale up their adoption of cytokine tests, but not all customers will adopt all tests – after two years, 50%

will purchase the 8-plex test, 25% the 10-plex and 20% the 10-plexQ. Ultimately, SQI may end up with fewer customers but generating significantly more project work than predicted, or more customers with fewer projects, but predicting the timing and scale of these contracts is difficult at this stage. Hence we adopt a base-case approach of one new customer per quarter, generating a sliding-scale of business, and retaining SQI's services for a number of years (Exhibit 8).

Exhibit 8: Forecast revenues from SQI's pharmaceutical customer business



Source: Edison Investment Research. Note: Revenues not risk-adjusted.

Sales of IVD tests to centralised laboratories

The market for autoimmune disease testing is estimated by SQI at >US$1bn. Most of this will be standard single-screening assays. The speciality autoimmune disease segment for multiple tests is dominated by three companies: Bio-Rad, Werfen-Inova and Phadia. Trinity Biotech, which acquired Immco Diagnostics (a niche company with US$12.5m annual turnover) for US$33m, puts the US market for lower throughput, speciality autoimmune diagnostics at US$250m, with 10%+ annual growth. SQI estimates that there are 1,600 clinical testing laboratories in North America doing >1m diagnostic tests per year. SQI estimates 12m celiac tests are conducted each year.

The multiplex, 96-well format test needs batch sample processing. This is typical for high-throughput labs with the demand to run several batches per day. The multiplexed format offers more high-value tests for less effort and at lower costs than multiple single-plex ELISA tests.

SQI is focused on three indications: celiac disease, vasculitis and lupus (Exhibit 9). These could be launched from 2014 onwards in Canada and the US. Tests for RA and IBD/Crohn's disease could follow. The FDA requires a test either to be equivalent to an existing approved test, allowing a faster 510(k) registration, or to show utility in a clinical trial, the PMA route. The route used by SQI is 510(k).

Exhibit 9: Current status of IVD pipeline

Product	Stage of development					
	Candidate panel	Proof-of-concept	Assay development	Automation	Validation	Approval/clearance
IgX PLEX RA (qualitative) (1)						
IgX PLEX RA (quantitative) (2)						
IgX PLEX Celiac (qualitative) (1)						
IgX PLEX Celiac (quantitative) (2)						
Ig_PLEX Celiac DGP (quantitative) (3)						
Ig_PLEX Vasculitis						
Ig_PLEX RA (quantitative) (3) – on hold						
Ig_PLEX Lupus – on hold						
Ig_PLEX IBD/Crohn's – on hold						

Source: Company documents. Notes: (1) Approved/cleared in the US and Canada; (2) Approved/cleared in Canada and EU; (3) Development for clearance in the US. 'On hold' means no material expenditure at present, but test is viable for future development.

Verification work on Ig_PLEX celiac DGP (deamidated gliadin peptide) is complete and SQI is conducting validation. If this is successful, Canadian and US regulatory review will occur in 2014. In

Canada, this should be rapid with approval available in Q1. FDA approval on a 510(k) basis is more uncertain and a mid-2014 approval is assumed with launch in summer 2014. Regulatory approvals for vasculitis and lupus assays should follow, in Q414 and in H115 respectively (Exhibit 10).

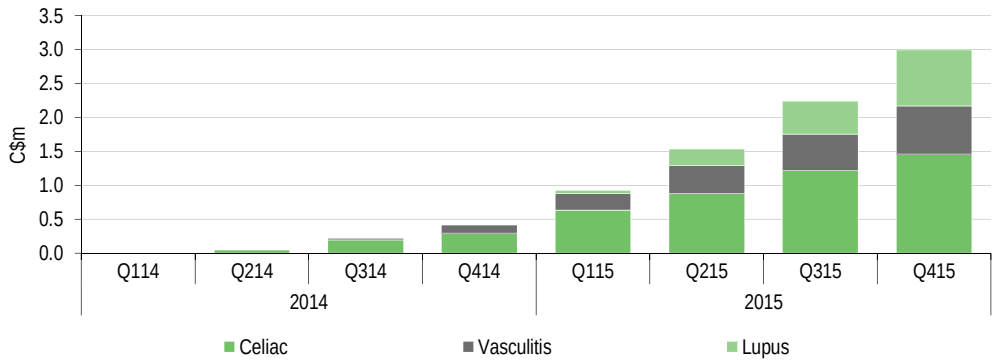
Exhibit 10: IVD regulatory approval timelines

		2014				2015			
		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Celiac	Canada	Licence							
	US		510(k)						
Vasculitis	Canada			Licence					
	US				510(k)				
Lupus	Canada				Licence				
	US					510(k)			

Source: Company documents

SQI plans to build relationships with major Canadian and US diagnostic laboratories during 2014 and 2015, and we assume that two new Canadian labs and four new US labs are secured as customers for each assay during a 12-month period. It is expected that by installing instruments in these labs, they will adopt multiple SQI tests as SQI gains regulatory approvals and builds up a menu of assays. Our IVD revenue forecasts in 2014 and 2015 are summarised in Exhibit 11.

Exhibit 11: Forecast revenues from SQI's IVD business



Source: Edison Investment Research. Note: Revenues not risk-adjusted.

SQI estimates that laboratories that use 4-plex assays and adopt a 10-plex Ig_PLEX test kit could significantly reduce processing costs as a result of the lower labour time (and therefore cost) required with Ig_PLEX. For illustrative purposes SQI estimates that a lab could cut its costs per celiac test by 43%, from C$40.00 to C$22.27, for a per-patient sample saving of ~$17.00.

Valuation

We value SQI at C$70m, or C$1.55 per share, based on a five-year (2014-18), risk-adjusted, sum-of-the-parts DCF valuation model. This includes a terminal value component (0.5% on 2018 free cash flow) and applies a standard 12.5% discount rate. The key components and assumptions with our model are summarised in Exhibit 12. Approximately two-thirds of value is attributed to the pharma customer business, which assumes consistent and timely execution of existing and new contracts.

The C$1.55 per share value is not a price target but a fair value for the stock today. Upside would come from a more rapid uptake of assays and machines from pharma customers and centralised laboratories than we currently model. This would also increase the probabilities of success for securing new business in later years, resulting in a higher valuation. It should be stressed that the risk-adjustment applied to cash flows from each business unit relates to commercial/competitive risk (ie ability to secure new customers in a competitive field), as opposed to technical risk

associated with gaining regulatory approvals, which we view as relatively low. Ultimately, SQI may end up with fewer customers but generating significantly more project work than predicted, or more customers with fewer projects, but predicting the timing and scale of these contracts is difficult at this stage. Hence we adopt a base-case approach of one new customer per quarter, generating a sliding-scale of business, and retaining SQI's services for a number of years.

Exhibit 12: Valuation metrics and key assumptions

Value driver	rNPV (C$m)	rNPV per share (C$)	2018 sales (C$m)*	Key assumptions
Custom pharma contracts (ADA assays)	20.6	0.46	17.6	One new customer per quarter; eight customers by end-2015; 20 customers by end-2018; C$25k initial fee; gradual increase revenue per customer ($200,000 in one to six months, to C$1.6m/year as retained basis); 65-100% sliding scale of probability of success.
SQiD equipment	0.9	0.02	0.5	Four SQiD-X (C$40,000 each), two SQiDlite (C$80,000 each) and one SQiDworks (C$200,000 each) machines sold in a 12-month period. 70-100% sliding scale of probability of success.
Custom pharma contracts (cytokine assays)	7.4	0.16	7.2	8-plex, 10-plex and 10-plex (Quant) available in Q114, Q314 and Q115, respectively; sliding scale of adoption, after two years, 50% will purchase 8-plex, 25% 10-plex and 20% 10-plexQ; 70-100% sliding scale of probability of success.
IVD	14.6	0.32	10.3	Two new labs/year in Canada; four new labs/year in US; all labs adopt all IVD assays when available: celiac (Q214; 100% probability), vasculitis (Q314; 65%) and lupus (Q115; 50%).
R&D	(12.5)	(0.28)		75-100% sliding scale risk-adjustment.
Admin	(8.4)	(0.19)		75-100% sliding scale risk-adjustment.
Cash	0.5	0.01		30 September 2013 net cash
Terminal value	46.4	1.03		0.5% annual growth on FY18 free cash flow, discounted at 12.5%, net of 30% tax
Valuation	69.6	1.55		45m shares outstanding (excludes dilution from warrants)

Source: Edison Investment Research. Note: *2018 sales unadjusted.

The price and value of each contract may vary significantly, depending on assay complexity and the clinical stage of the subject product. Conversely, should the rate of new business not materialise as predicted, this would have a negative impact. Our per-share valuation does not include any potential dilution from 14m warrants (exercise price range: C$0.75 to C$5.00; expiry range: May 2014 to October 2015) in issue or 2.3m outstanding share options.

Sensitivities

The publication by Algorithme and BMS of validation data on Ig_PLEX, and the existing deals with Isis Pharmaceuticals and three further pharma customers, reduces the investor risk profile as they provide independent validation of SQI's technology and its utility. Technical risk appears moderate as the majority of assay targets are clinically accepted, so there should be no problem about gaining regulatory approvals, physician acceptance and reimbursement. Conversely, at this stage, with modest revenues to date, there is reasonable commercial risk in SQI achieving the near-term sales targets we have modelled. The diagnostics field is highly competitive, with a number of large companies able to apply significant resources to promotion and commercialisation activities. The challenge for SQI will be in communicating and convincing customers of the improved accuracy and efficiency of its Ig_PLEX technology. We have assumed a consistent stream of new customers and a timely execution on these contracts, such that any significant delays in uptake could have a negative impact. SQI's pipeline of new customers and new assays looks promising, so delivery on these fronts, particularly over 2014 and 2015, could significantly improve valuations and sentiment.

Financials

We estimate SQI ended fiscal Q114 (31 December 2013) with C$0.5m in cash (vs $1.4m at 30 Sept 2013). This highlights an imminent financing requirement, and we have assumed C$4m is raised in 2014, nominally attributed to long-term debt. SQI last raised funds in May 2013, realising C$3.5m (net) from the sale of 5.1m shares at C$0.75 and 5.1m warrants (exercisable at C$1.10, expire 1 May 2015). Revenues in FY13 were C$3,000 (vs C$12,000 in FY12). We model risk-adjusted

revenues in FY14 and FY15 at C$1.6m and C$11.4m, respectively. This is primarily driven by the pharma customer business, assuming timely execution of existing and prospective contracts. R&D expenses in FY13 were C$3.9m, and we forecast modest reductions in FY14 and FY15 to C$3.7m and C$3.8m, respectively. Importantly, even on a risk-adjusted revenue basis, our model indicates that SQI could achieve profitability by the end of 2015.

Exhibit 13: Financial summary

C$'000s	2011	2012	2013	2014e	2015e
Year end 30 September	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue	36	12	3	1,615	11,448
Cost of Sales	0	0	0	(565)	(4,007)
Gross Profit	36	12	3	1,050	7,441
Research and development	(6,295)	(3,890)	(3,858)	(3,687)	(3,797)
Corporate and general	(3,835)	(2,131)	(1,928)	(1,879)	(1,973)
Sales and marketing	(460)	(288)	(449)	(484)	(546)
EBITDA	(10,888)	(6,734)	(6,695)	(5,379)	820
Operating Profit (before GW and except.)	(10,432)	(6,198)	(6,129)	(4,886)	1,251
Intangible Amortisation	(122)	(99)	(103)	(114)	(126)
Exceptionals/Other	0	0	0	0	0
Operating Profit	(10,554)	(6,297)	(6,232)	(5,000)	1,125
Net Interest	61	11	25	(23)	(74)
Other	(251)	(25)	0	0	0
Profit Before Tax (norm)	(10,371)	(6,187)	(6,104)	(4,908)	1,177
Profit Before Tax (FRS 3)	(10,744)	(6,311)	(6,207)	(5,023)	1,051
Tax	0	0	0	0	0
Deferred tax	0	0	0	0	0
Profit After Tax (norm)	(10,371)	(6,187)	(6,104)	(4,908)	1,177
Profit After Tax (FRS 3)	(10,744)	(6,311)	(6,207)	(5,023)	1,051
Average Number of Shares Outstanding (m)	33.4	37.4	42.0	45.6	47.0
EPS - normalised ($)	(0.31)	(0.17)	(0.15)	(0.11)	0.03
EPS - FRS 3 ($)	(0.32)	(0.17)	(0.15)	(0.11)	0.02
Dividend per share ($)	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET					
Fixed Assets	3,468	3,322	3,082	2,866	2,710
Intangible Assets	615	685	775	859	936
Tangible Assets	2,853	2,637	2,307	2,007	1,774
Other	0	0	0	0	0
Current Assets	1,266	4,208	1,724	1,427	3,153
Stocks	138	54	56	813	769
Debtors	277	135	253	253	253
Cash	851	3,818	1,415	361	2,131
Other	0	201	0	0	0
Current Liabilities	(2,588)	(1,018)	(454)	(454)	(454)
Creditors	(2,588)	(1,018)	(454)	(454)	(454)
Short term borrowings	0	0	0	0	0
Long Term Liabilities	0	0	0	(4,000)	(4,000)
Long term borrowings	0	0	0	(4,000)	(4,000)
Other long term liabilities	0	0	0	0	0
Net Assets	2,146	6,512	4,352	(162)	1,409
CASH FLOW					
Operating Cash Flow	(8,065)	(6,692)	(5,522)	(4,662)	2,171
Net Interest	0	0	0	0	0
Tax	0	0	0	0	0
Capex	(750)	(432)	(429)	(391)	(401)
Acquisitions/disposals	2	0	0	0	0
Financing	246	10,091	3,548	0	0
Dividends	0	0	0	0	0
Other	0	0	0	0	0
Net Cash Flow	(8,567)	2,967	(2,403)	(5,054)	1,770
Opening net debt/(cash)	(9,408)	(851)	(3,818)	(1,415)	3,639
Exchange rate movements	0	0	0	0	0
Other	10	0	0	0	0
Closing net debt/(cash)	(851)	(3,818)	(1,415)	3,639	1,869

Source: SQI accounts, Edison Investment Research. Note: revenues are risk-adjusted. Model does not include any potential dilution from 14m warrants (exercise price range C$0.75 to C$5.00) in issue or 2.3m outstanding share options.

Contact details	Revenue by geography
36 Meteor Drive Toronto, Ontario M9W 1A4 Canada +1 (416) 674-9500 www.sqidiagnostics.com	N/A

CAGR metrics		Profitability metrics		Balance sheet metrics		Sensitivities evaluation	
EPS 10-14e	N/A	ROCE 13e	N/A	Gearing 13e	N/A	Litigation/regulatory	◖
EPS 12-14e	N/A	Avg ROCE 10-14e	N/A	Interest cover 13e	245.2	Pensions	○
EBITDA 10-14e	N/A	ROE 13e	N/A	CA/CL 13e	3.8	Currency	◖
EBITDA 12-14e	N/A	Gross margin 13e	N/A	Stock days 13e	N/A	Stock overhang	●
Sales 10-14e	N/A	Operating margin 13e	N/A	Debtor days 13e	N/A	Interest rates	○
Sales 12-14e	N/A	Gr mgn / Op mgn	N/A	Creditor days 13e	N/A	Oil/commodity prices	○

Management team

Chief executive officer: Andrew Morris	Vice president, technology: Kate Smith
Andrew joined SQI in 2004 as CFO, becoming CEO in June 2013. Before SQI, he led the Corporate Finance Life Sciences group at Ernst & Young. He has a background in medical research, capital markets and corporate finance (Scotia Capital).	Kate joined SQI in January 2005. She was previously at Visible Genetics, NeXT Computer and Lucasfilm. She holds a bachelor's degree in computer science from Brown University.
Chairman: Claude Ricks	**Vice president, R&D: Jaymie Sawyer**
Claude joined SQI in September 2003 and was CEO between 2006 and June 2013, when he then became chairman. Before SQI, Claude was a senior manager working in technology turnarounds (Oasis Technology/Solect Technology) and in global consulting firms (A.T. Kearney).	Jaymie joined SQI in October 2010. Previously, she was director, reagent and assay development at Becton Dickinson. Also a founding member of Motorola Biochip systems. She holds a PhD in genetics from the University of Wisconsin.

Principal shareholders	(%)
Cumberland Private Wealth Management	12.67
Focus Asset Management	10.40
Claude Ricks (chairman)	4.43
Saied Nadjafi (non-exec director)	4.29
Dr Peter Lea (founder)	3.92
David Williams (non-exec director)	1.06

Companies named in this report

Bristol-Myers Squibb (BMY); Isis Pharmaceuticals (ISIS); Bio-Rad Laboratories (BIO); Illumina (ILMN)

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