

SQL Diagnostics

Company update

Encouraging new deal flow

SQL has had positive traction in recent months with the signing of two new customers, a top 10 global pharma company and a UK-based DNA specialist. The latter will use SQL's systems for pathogen detection, potentially opening the door to a new application for SQL's technology. These deals counteract what has proven to be a more protracted timeframe than anticipated for the full commercialisation of SQL's diagnostics platform. After pushing back the phasing of contracts converting to full commercial terms, our revised valuation of SQL is C\$60m (vs C\$76m previously) or C\$1.07 per share (vs C\$1.35).

Year end	Revenue (C\$m)	PBT* (C\$m)	EPS* (c)	DPS (c)	P/E (x)	Yield (%)
09/12	0.0	(6.2)	(16.54)	0.0	N/A	N/A
09/13	0.0	(6.1)	(14.55)	0.0	N/A	N/A
09/14e	0.1	(5.2)	(10.32)	0.0	N/A	N/A
09/15e	5.7	(0.6)	(1.06)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding intangible amortisation, exceptional items and share-based payments. Revenues are risk-adjusted.

Contract to automate pathogen detection assays

SQL has signed a deal with a UK-based DNA company to automate DNA-based pathogen detection assays. The tests will run off SQL's SQiDlite system and are capable of identifying multiple pathogens simultaneously, offering a considerable advantage in speed and accuracy compared with current methods, which require traditional plate cultures. Pathogen detection represents a new application for SQL's automated system and could lead to the additional commissioning of tests from this customer as well as other companies with similar testing needs. For this first deal SQL can expect payment when the first automated assay has been demonstrated on its SQiDlite platform, with subsequent compensation as tests are commercialised.

Signing of top-10 pharma company for multiplexing

Generating substantial revenues from pharma customers for SQL's multiplexed assay technology is key to the investment case. In its fiscal Q314 (30 June), SQL announced a deal with a top-10 pharma company, now referred to as 'Pharma 4', to develop two custom multiplex anti-drug antibody assays. The customer is using SQL's assays for one of its established drugs to assess the performance of SQL's technology. Successful validation could result in significantly more work for SQL to supply testing for Pharma 4's many early-stage drug candidates.

Valuation: Adjusted to C\$60m or C\$1.07 per share

We have adjusted our forecasts to compensate for a more prolonged timeframe now anticipated for generating substantial revenues from pharmaceutical company contracts. This is partially offset by revenue expected from the two new deals announced in recent months. The per-share value reduces to C\$1.07 (vs C\$1.35). We value SQL based on a five-year (2014-18), risk-adjusted, sum-of-the-parts DCF valuation model applying a standard 12.5% discount rate. Approximately two-thirds of value is attributed to the pharma customer business.

Healthcare equipment & services

29 September 2014

Price **C\$0.38**

Market cap **C\$21m**

C\$1.1/US\$

Net cash (C\$m) at 30 June 2014 3.0

Shares in issue 56.3m

Free float 86%

Code SQD

Primary exchange TSX-V

Secondary exchange OTCQX: SQIDF

Share price performance



% 1m 3m 12m

Abs 8.6 0.0 (48.0)

Rel (local) 12.9 0.0 (55.5)

52-week high/low C\$0.90 C\$0.30

Business description

SQL Diagnostics is a Canadian diagnostics company. It 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 coeliac, lupus and vasculitis.

Next events

Pharma customer deals H214

FDA 510(k) approval of coeliac test H214

FY14 results December 2014

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Two new contracts signed

Deal to automate pathogen detection assays

In August SQI entered into an agreement with a UK-based company to exploit SQI's multiplexing technology to automate DNA-based pathogen detection assays. SQI will be paid in the initial phases to deliver an automated working prototype of one of the customer's assays that will be operational on the company's SQiDlite system. The successful completion of demonstration of assay 1 is expected to result in a contract to automate and manufacture the fully automated test and systems and other tests for this customer.

This first assay to be automated will be used to identify pathogens in raw milk from dairy cows. Currently this work is conducted using traditional plate cultures while SQI's automated technology has the potential to work much faster and more accurately and is capable of identifying multiple pathogens simultaneously. The UK-based customer is also developing assays for agriculture, food safety, and human pathogen testing for the screening of high volumes of samples.

SQI management expects revenue recognition in the latter part of this calendar year as spelled out in the service agreement, with additional sales to follow in 2015 from equipment and reagents. While it is still early days for this new application of SQI's multiplexing technology, we are cautiously optimistic that the agreement could prove a new avenue for the use of SQI's platform, which could not only lead to the additional commissioning of tests from its existing customer, but also provide automated diagnostics solutions for more companies with similar testing needs.

Sixth pharma customer for custom multiplex assays

In the third quarter SQI announced the addition of its sixth customer for its custom multiplex antibody assays, a top 10 pharmaceutical company globally. 'Global Pharma 4' contracted SQI to develop and validate two custom multiplex anti-drug-antibody (ADA) assays¹ – tests that are commonly designed to measure and characterise the animal and human response to a drug. Management recently reported on the progress of this newest pharma contract, conveying its conviction that performance so far has exceeded the customer's expectations. SQI supplied Pharma 4 with initial data from prototype development work, meeting important performance criteria laid out in its agreement. The customer is evaluating two assays created by SQI using one of its already established drugs to assess the performance of SQI's technology.

SQI's ability to secure this new customer is encouraging and management suggests the initial work being conducted for Pharma 4 could provide a good entry point for a much larger opportunity within the collaboration. We believe that success early on could well unlock the potential to supply DNA testing for other of Pharma 4's many early-stage drug candidates.

Our forecasts assume ongoing deal flow

The addition of two pharmaceutical collaborations over the past four months is encouraging and an important validation of SQI's commercial and business strategy. These contracts with pharmaceutical companies typically involve an initial validation phase, but once this hurdle is cleared, there is significant potential in SQI establishing an extensive and retained portfolio of business with the company.

Our forecast model assumes that SQI secures a steady stream of new clients and then converts existing customer contracts onto commercial terms. We assume revenue received from each

¹ Anti-drug antibodies (ADAs) are a key immune response that can neutralise a biological therapeutic and are common when a biological drug is repeatedly given. When developing a new biological drug candidate, pharma/biotech companies need to be able to fully characterise the patient's immune response to the agent.

customer will gradually increase, from relatively modest amounts to ~C\$1.5m per year on a retained basis.

The status of SQI's existing pharma customer contracts is summarised in Exhibit 1. For confidentiality reasons, these customers often cannot be named, which is fairly typical of contracts in the diagnostics sector. To date SQI's customer base includes four of the world's 50 largest pharmaceutical and biotech companies. In addition to the two new contracts, Global Pharma 1 is in talks over next steps on completion of the epitope mapping and we expect an update on commercialisation plans in the current calendar year. However, we note progress with other collaborators has been somewhat slower than expected. Management has indicated that work with Global Pharma 3 and Global Pharma 2 is being deferred for the time being, due to specific internal issues within each of these organisations. We continue to see the potential of between C\$1-2m per pharma customer however, and have adjusted our models to the new time frame.

Exhibit 1: 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 (various Global Pharma)						
Heparin Immunogenicity ('HIT') Assay						
Global Pharma 1						
Global Pharma 2						
Isis Pharmaceuticals						
Global Pharma 3						
Global Pharma 4						
DNA Company (UK)						
Source: Company documents, Edison Investment Research						

Management is also actively pursuing strong leads that have been generated from a number of companies, including those focused on oncology and vaccines. We therefore see the possibility of the closure of at least one more deal for ADA and a novel biomarker development project by the end of the year.

Continued progress in IVD testing

SQI continues to progress its menu of *in vitro* diagnostic (IVD) tests, focused on autoimmune disorders, marketing to centralised diagnostics laboratories in the US and Canada that conduct high-throughput screening assays. The market represents a considerable opportunity (there are more than 1,500 diagnostic laboratories in North America); however, it remains highly competitive.

Following the licensing in Canada of its multiplexed DGP panel in coeliac disease in February, SQI management is in final talks with the FDA for marketing clearance in the US for coeliac disease and expects an imminent decision. SQI's IVD diagnostics work as part of a menu of tests on an automated system. We therefore believe that most labs will want at least one more product for inclusion as part of the bundling of services. We expect first sales will likely start feeding through on regulatory clearance of SQI's next test kit for vasculitis, which will be filed by early 2015 in both the US and Canada. In conjunction with the roll out of its first systems, SQI is hiring its first salesperson dedicated to IVD systems. SQI's tests offer considerable cost savings over current tests on the market and the additional sales support should help secure steady sales take up. SQI estimates that a lab could cut its costs per test for coeliac by 43%, from C\$40.00 to \$C22.27, for a saving per sample of ~\$17.00.

In addition to its assay for coeliac disease and vasculitis, SQI is building a pipeline of other autoimmune assays for use on its automated system, including a quantitative 12-plex panel for lupus, a quantitative 3-plex panel for vasculitis, and an 8-plex panel for Crohn's disease (held for

the time being at the development stage). The status of SQI's IVD portfolio is summarised in Exhibit 2.

Exhibit 2: Stage of development of SQI's IVD tests						
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 Coeliac (Qualitative) (1)						
IgX PLEX Coeliac (Quantitative) (3)						
Ig_PLEX Coeliac DGP (Quantitative) (3)						
Ig_PLEX Vasculitis						
Ig_PLEX Lupus						
Ig_PLEX RA (Quantitative) (3) on hold						
Ig_PLEX IBD/Crohn's on hold						

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

Valuation

We have adjusted our forecasts to compensate for a slightly more protracted timeframe now anticipated for future revenues from pharmaceutical company contracts. The key changes to our valuation and financial models are summarised in Exhibit 3.

Exhibit 3: Summary of forecast changes	
Custom pharma contracts (ADA assays)	Phasing of contracts moving to full commercial terms pushed back two quarters.
SQiD equipment	No SQiD machine sales in 2014 (C\$380k in fiscal 2015).
Custom pharma contracts (cytokine assays)	Phasing of cytokine assay orders shifted back two quarters.
IVD: Coeliac test	Removed Canada lab contract in FY14, first one in fiscal Q115; removed one US lab contract in FY14. Forecast slower initial uptake.
IVD: Vasculitis	Pushed back vasculitis test launch by three quarters to Q215. Forecast slower initial uptake.
IVD: Lupus	Pushed back lupus test launch by two quarters to Q315. Forecast slower initial uptake.

Source: Edison Investment Research

These changes are partially offset by revenue expected from the recently announced deal with the UK-based DNA company. The per-share value reduces to C\$1.07 (vs C\$1.35). We value SQI 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 displayed in Exhibit 4.

Approximately two-thirds of value is attributed to the pharma customer business, which assumes consistent execution of existing and new contracts.

Exhibit 4: SQI valuation model and key drivers

Value driver	rNPV (C\$m)	rNPV per share (C\$)	2018 sales (C\$m; unadjusted)	Key assumptions
Custom pharma contracts (ADA assays)	20.8	0.37	18.0	One new customer per quarter; seven 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%-95% sliding scale of probability of success.
SQiD equipment	1.0	0.02	0.7	4x SQiD-X (C\$40,000), 2x SQiDlite (C\$80,000) and 1x SQiDworks (C\$200,000) machines sold in a 12-month period. 70-85% sliding scale of probability of success.
Custom pharma contracts (cytokine assays)	5.7	0.10	7.2	8-plex, 10-plex and 10-plex (Quant) available in Q314, Q115 and Q215, respectively; sliding scale of adoption, after two years, 50% will purchase 8-plex, 25% 10-plex and 20% 10-plexQ; 70-95% sliding scale of probability of success.
IVD	7.6	0.13	5.4	Two new labs/year in Canada; four new labs/year in US; all labs adopt all IVD assays when available: coeliac (Q414; 85% probability), vasculitis (Q115; 65%).
R&D	(10.8)	(0.19)		75-100% sliding scale risk-adjustment.
Admin	(6.4)	(0.11)		75-100% sliding scale risk-adjustment.
Cash	1.6	0.03		Estimate for end-FY14 (30 September 2014).
Terminal value (0.5%)	40.6	0.72		0.5% annual growth on FY18 free cash flow, discounted at 12.5%, net of 30% tax.
Valuation	60.1	1.07		56.3m shares outstanding (excludes dilution from 26m warrants and 2.6m share options).

Source: Edison Investment Research

The price and value of each pharma contract may vary significantly, depending on assay complexity and the clinical stage of the subject product. Hence we adopt a base-case approach generating a sliding scale of business, and retaining SQI's services for a number of years. Should the rate of new business revenues not materialise as predicted, this would have further negative impacts. Our per-share valuation does not include any potential dilution from 26m warrants (exercise price range: C\$0.50 to C\$5.00; 2.6m outstanding share options).

On 17 September 2014 SQI began trading on the OTCQX², an investor-focused US exchange. While this has no impact on our model or valuation, we view the listing as a positive step, which should serve to increase awareness of the company in the US investment community.

Sensitivities

The challenge for SQI is to convert its technical and competitive advantages into revenues. SQI's technology has gained independent validation through multiple pharma customer contracts and the publication of certain studies (eg Algorithme and BMS). Technical risk therefore appears moderate as the majority of assay targets are clinically accepted, so there should be no problem gaining regulatory approvals, physician acceptance and reimbursement. Additionally, 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.

Conversely, at this stage, with modest revenues to date, there is reasonable commercial risk in SQI achieving the adjusted 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 (pharma companies, CROs and diagnostic laboratories) of the improved accuracy and efficiency of its Ig_PLEX technology. We have assumed a consistent stream of new customers, however any significant delays in uptake could have a negative impact on our valuation. SQI's pipeline of new customers and new assays looks promising, so delivery on these fronts, particularly over 2015, could significantly improve valuations and sentiment.

² Companies need to meet pre-specified financial statement requirements and be compliant with US securities laws in order to qualify for the OTCQX.

Financials

SQI recorded revenue of C\$32,000 in fiscal Q314, a significant increase from the C\$18,000 and C\$2,000 in revenues in fiscal Q214 and Q1 respectively. We expect a continued increase of the top line for the remainder of the year and throughout fiscal 2015. We model risk-adjusted revenues in FY14 and FY15 at C\$115k and C\$6m, respectively (vs C\$1.5m and C\$11.4m previously). This is primarily driven by the pharmaceutical customer business.

Our forecasts indicate that SQI could achieve profitability in the fourth quarter of fiscal 2015 (year end September), reaching break-even by mid-year, should the revenue forecasts be met.

SQI ended fiscal Q314 (30 June 2014) with C\$3.0m in cash. In the second quarter of 2014 management implemented a cost-cutting plan, which included reductions in R&D expenditure, general cost containment efforts and staff cuts. Company expenditure is therefore now at a run rate of ~C\$5m on an annualised basis, including ~C\$1m in corporate and marketing initiatives, ~C\$3.5m for R&D activities to build an assay menu (key to long-term IVD growth), and the remainder for working capital and other general purposes.

Exhibit 5: Financial summary

	C\$000s	2012	2013	2014e	2015e	2016e
Year end 30 September		IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS						
Revenue		12	3	115	5,711	18,622
Cost of Sales		0	0	0	(857)	(2,793)
Gross Profit		12	3	115	4,855	15,828
Research and development		(3,890)	(3,858)	(3,532)	(3,603)	(3,603)
Corporate and general		(2,131)	(1,928)	(1,440)	(1,368)	(1,395)
Sales and marketing		(288)	(449)	(614)	(675)	(709)
EBITDA		(6,734)	(6,695)	(5,771)	(996)	9,884
Operating Profit (before GW and except.)		(6,198)	(6,129)	(5,258)	(598)	10,249
Intangible Amortisation		(99)	(103)	(119)	(123)	(128)
Exceptionals/Other		0	0	0	0	0
Operating Profit		(6,297)	(6,232)	(5,377)	(721)	10,121
Net Interest		11	25	20	6	12
Other		(25)	0	0	0	0
Profit Before Tax (norm)		(6,187)	(6,104)	(5,238)	(591)	10,261
Profit Before Tax (FRS 3)		(6,311)	(6,207)	(5,357)	(714)	10,133
Tax		0	0	0	0	0
Deferred tax		0	0	0	0	0
Profit After Tax (norm)		(6,187)	(6,104)	(5,238)	(591)	10,261
Profit After Tax (FRS 3)		(6,311)	(6,207)	(5,357)	(714)	10,136
Average Number of Shares Outstanding (m)		37.4	42.0	50.7	55.4	55.9
EPS - normalised (c)		(16.54)	(14.55)	(10.32)	(1.06)	18.19
EPS - FRS 3 (\$)		(0.17)	(0.15)	(0.11)	(0.01)	0.18
Dividend per share (\$)		0.0	0.0	0.0	0.0	0.0
BALANCE SHEET						
Fixed Assets		3,322	3,082	2,739	2,514	2,325
Intangible Assets		685	775	837	900	962
Tangible Assets		2,637	2,307	1,902	1,614	1,362
Other		0	0	0	0	0
Current Assets		4,208	1,724	1,950	1,726	12,318
Stocks		54	56	33	245	241
Debtors		135	253	303	303	303
Cash		3,818	1,415	1,614	1,178	11,774
Other		201	0	0	0	0
Current Liabilities		(1,018)	(454)	(369)	(369)	(369)
Creditors		(1,018)	(454)	(369)	(369)	(369)
Short term borrowings		0	0	0	0	0
Long Term Liabilities		0	0	0	0	0
Long term borrowings		0	0	0	0	0
Other long term liabilities		0	0	0	0	0
Net Assets		6,512	4,352	4,320	3,871	14,274
CASH FLOW						
Operating Cash Flow		(6,692)	(5,522)	(4,585)	(140)	10,900
Net Interest		0	0	0	0	0
Tax		0	0	0	0	0
Capex		(432)	(429)	(289)	(296)	(304)
Acquisitions/disposals		0	0	0	0	0
Financing		10,091	3,548	5,073	0	0
Dividends		0	0	0	0	0
Other		0	0	0	0	0
Net Cash Flow		2,967	(2,403)	199	(436)	10,596
Opening net debt/(cash)		(851)	(3,818)	(1,415)	(1,614)	(1,178)
HP finance leases initiated		0	0	0	0	0
Exchange rate movements		0	0	0	0	0
Other		0	0	0	(0)	0
Closing net debt/(cash)		(3,818)	(1,415)	(1,614)	(1,178)	(11,774)

Source: SQI accounts, Edison Investment Research. Note: Revenues are risk-adjusted. Our model does not include any potential dilution from 26m warrants (exercise price range C\$0.65 to C\$5.00) in issue or 2.6m outstanding share options.

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