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New Government Funding for Medical Technology R&D

Ontario and U.S. Programs offer different approaches to help fund innovation in medical technology

In this bulletin, we highlight two new government funding incentive programs for private companies in the biotech / medical-device sectors. The “Learn More” area at the end of this article provides links to additional detailed information on this topic.

One of these programs – HTCP – will distribute \$21 million to collaborative projects undertaken by private / private or private / public consortiums in the province of Ontario, Canada. The other will distribute \$1 billion of new R&D funding to small- and medium-sized U.S. companies through a new, federally administered tax credit program called *Investment Credit For Qualifying Therapeutic Discovery Projects*. The U.S. program is particularly intriguing in that it provides a cash refund – essentially a grant – and may well signal renewed appetite for genuine improvement in that country’s R&D tax credit system.

The advent of these new incentives highlights governments’ interest in stimulating a key sector of the knowledge economy while at the same time coming up with ways of containing health care costs. Ontario’s publicly funded health care system represents a huge component of the government’s annual budget: presently about 45% of the province’s total program spending and projected to increase to 70% by 2022 if left unchecked. With the implementation of a public health care scheme in the U.S. on the horizon, Washington must likewise see tangible practical value in new health care technologies.

There is no doubt that the U.S. funding is immense in comparison to Ontario's latest effort through HTCP, however there are some "countervailing" factors built in to the Canadian tax system that might level the playing field somewhat.

While the U.S. also offers various R&D tax credits at the federal level, the federal program is not (as of this writing) permanent and the benefits are frequently unavailable from one year to the next. However, it is notable that an increasing number of states are now offering their own R&D tax credit and that many of those are providing R&D benefits in the form of cash refunds.

However, the existing R&D tax credits schemes in both Canada and the U.S. are often of limited use to start-up biotech companies ...

Limitations of Existing R&D Tax Credits in the Biotech Sector

In the U.S., the U.S. federal R&D credit is not refundable, meaning that it is only useful to companies that make profit and pay taxes – which leaves out many start-up technology companies.

Canada on the other hand offers one of the richest R&D tax credit programs in the world and it is both permanent and stable. At the federal level, Canada offers a permanent R&D tax credit that pays refundable cash benefits to many "private" companies regardless of whether they have taxable income or not. Total disbursements from this program amount to about \$4 billion per year. Furthermore most Canadian provinces – including Ontario – provide "state level" R&D tax credits on top of the federal benefit. Ontario's R&D tax credit can provide a cash refund to both private and public companies. In an average year, such tax credit cash refunds distributed to companies in Ontario amount to about \$300M.

Unfortunately when it comes to R&D tax credits, many Canadian biotech companies are not much better off than those in the U.S. This is because a disproportionate number of biotech companies (including many pre-commercial start-ups) are public – not private – and therefore not eligible to receive their Canadian R&D tax credit in the form of a cash refund. The situation is slightly better for smaller publicly owned biotech companies located in Ontario where a full cash refund R&D tax credit of up to \$300K is available to any company (public or private) that has taxable income <\$500K and taxable capital <\$25M.

So understanding that R&D tax credits are often of limited value to the biotech sector, let's take a closer look at these two new funding programs: The first is a grant / loan program called HTCP by which \$21M in funding from the Ontario government is delivered through quasi-governmental agency called HTX. The other is a novel U.S. federal tax / grant program called *Investment Credit For Qualifying Therapeutic Discovery Projects* that offers \$1B to U.S. SME's over the next two years.

Ontario – HTCP

In April 2010, the Ontario Government announced the *Health Technology Commercialization Program* (HTCP) to be funded and administered by the Health Technology Exchange (HTX), a division of the Ministry of Research and Innovation (MRI). This program will distribute approximately \$14.3M to private sector companies that form “collaborations” leading to enhanced development of Medical and Assistive Technology (MAT):

\$6.5 Million to Small and Medium Enterprises (SME)

\$7.8 Million to Multi National Enterprises (MNE)

The remaining funds are for the administration of the program

The majority of HTCP funding will be offered in the form of repayable loans or convertible debentures covering up to 50% of the total project budget. A smaller portion of the funding will also be available in the form of non-repayable grants covering up to 15% of the total project budget.

Eligible “collaborations” may include another corporation (local or multi-national), an academic institutions or a healthcare institution in Ontario. The collaborating partner is expected to provide matching funds. These collaborations can be informal “joint ventures” – there is no need for the formation of a legal partnership.

Project Area	Max. Total Project Budget
Early Stage Product Development	\$200K
Advanced Stage Product Development	\$250 K to \$1,500K
Clinical Evaluation or Technical Assessment	\$200K
Sales and Marketing Efforts	\$100K

Any company considering using HTCP funding should carefully review the potentially negative effect of this funding on their R&D tax credits (i.e. SR&ED). Companies that receive SR&ED benefits as a cash refund (i.e. CCPCs) could suffer reduced SR&ED benefits as a result of receiving the HTCP funding – which would make the whole process of questionable value (at least in purely fiscal terms). Companies that do not receive SR&ED as a cash refund (i.e. public companies and other non-CCPCs), would also suffer loss of SR&ED benefits, however the amount so lost would be lower due to lower benefit rate for these companies and the HTCP would provide an immediate source of cash, versus ITCs which many non-CCPCs (i.e. public or foreign-owned corporations, partnerships) can’t monetize anyway.

All applicants to HTCP must show their proposed project is aimed at producing tangible economic benefits for Ontario in term of job creation and sustainable long-term commercial activity.

U.S.A. – Investment Credit For Qualifying Therapeutic Discovery Projects

In March 2010, the U.S. Federal Government enacted a package of health care reform legislation that included an *Investment Credit For Qualifying Therapeutic Discovery Projects*, which offers a 50% tax credit or tax-free grant exclusively to small- and medium-sized companies located in the U.S. It is available to both traditional C corps and pass-through entities (partnerships, S corps) providing total employment is 250 persons or less.

The program is aimed at biotech R&D projects with any of the following objectives:

- to prevent, detect, or treat chronic or acute diseases and conditions
- to reduce long-term health care costs in the United States
- to significantly advance the goal of curing cancer

Despite its relatively small size, there are three things that put this new U.S. tax credit program ahead of Canada's SR&ED. First – at 50% it exceeds the roughly 40% rate for a CCPC in Ontario. Second – it offers a refundable cash benefit to both private and public companies whereas in Canada refundable benefits are available only to CCPCs which leaves out many biotechs. Third – being a tax-free grant or tax credit, it does not require recognition as revenue in the year that it is received, whereas in Canada the SR&ED benefits are themselves taxable in the year received.

The downside of this unique U.S. tax credit is that it only available for two years (2009 and 2010) and the total amount of available funding is capped at maximum of \$1B. Furthermore it is “competitive”, which means companies must apply and be approved in advance. In the Canadian SR&ED system, claims are made in arrears at year-end and there is no upper limit in respect to the maximum amount of benefit available.

Applications to the *Investment Credit For Qualifying Therapeutic Discovery Projects* program are made by means of IRS form #8942 which will be available June 21, 2010 and must be submitted no later than July 21, 2010. Further detailed instructions are provided in IRS Notice 2010-45. The IRS will review submissions and announce the successful applicants by October 29, 2010.

The U.S. is moving very quickly to enable this program and to make funding approvals. Congressional directives gave the administration only 60 days to have the program up and running and applications must be approved within 30 days. That too defines the U.S. program, as often programs in Canada can take extended amounts of time for review and approval.

Learn More...

- > Scitax survey of International R&D Tax Credits:
<http://www.scitax.com/pdf/Scitax.International.RD.Tax.Credit.Survey>
- > Scitax publication Introduction to R&D Tax Credits in Canada with Worked Examples
<https://www.scitax.com/pdf/Introduction.to.R&D.Tax.Credits.in.Canada.SCITAX.Apr-2010.pdf>
- > “Funding” page of Ontario’s HTX organization that describing the HTCP program
<https://www.htx.ca/FundingList.aspx>
- > Description of Investment Credit For Qualifying Therapeutic Discovery Projects in notice 10-45 at U.S. Internal Revenue Service
<http://www.irs.gov/pub/irs-drop/n-10-45.pdf>
- > Conference Board of Canada Analysis of Health Care Spending in Ontario 2010 budget
http://www.conferenceboard.ca/topics/economics/budgets/ontario_2010_budget.aspx

For more information on this topic, contact:

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About Scitax...

Scitax Advisory Partners is a professional services firm with specialist expertise in Scientific Research and Experimental Development (SR&ED) tax credits.

We offer a team of senior technical consultants all of whom have ten or more years experience in the SR&ED field. All Scitax technical consultants have engineering or science backgrounds and at least twenty years industry experience in their particular field prior to consulting.

Our primary function is to produce a technical submission package that most effectively communicates your SR&ED claim to CRA in a way that highlights eligibility and expedites processing. We assist you in identifying and preparing all required documentation including project technical descriptions, cost schedules, and everything else your tax preparer needs to file the claim. Once your claim is filed, Scitax will advocate for you with CRA and help you negotiate fair settlement of your claim.

While we normally work with our client's existing tax advisors, our affiliated firm Cadesky and Associates can provide a full package of tax services if required.



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