

Transitioning from Genomics to an Impact in the Clinic

A Questions and Answers Session with Isaac Ro of Sema4

A LONG-TERM TREND has been noted of companies founded in the genomic era that are now transitioning from data providers to having a broad impact in the clinic. For

example, a recent press release¹ announced that Sema4 and OPKO Health recently signed a definitive agreement for Sema4 to acquire OPKO's wholly owned subsidiary, GeneDx,

a leader in genomic testing and analysis. Following completion of the acquisition, Sema4 will be optimally positioned to partner with health systems and biopharma companies ▶

Don't let patients with **TARGETABLE MUTATIONS** get lost in the crowd

METex14

There are ~4,000 to 5,000 patients with **METex14** in mNSCLC per year in the United States.¹⁻²



Nearly 1 in 2 patients with mNSCLC may have a targetable oncogenic mutation,³⁻¹⁰ but many patients are not tested for all potential targets (prevalence of **METex14** ~3%).^{4,9,11-15}



The National Comprehensive Cancer Network® (NCCN®) recommends testing for ALK, KRAS, BRAF, EGFR, **METex14**, NTRK1/2/3, RET, ROS1 and PD-L1 in eligible newly diagnosed mNSCLC patients.^{16*}

**Up-front broad molecular profiling may help optimize
first-line treatment for mNSCLC.**

MET, mesenchymal-epithelial transition; METex14, MET exon skipping; mNSCLC, metastatic non-small cell lung cancer.

**The NCCN Guidelines® for NSCLC provide recommendations for certain individual biomarkers that should be tested and recommend testing techniques but do not endorse any specific commercially available biomarker assays or commercial laboratories.*

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References: 1. Wang RG, et al. Clinicopathological implications of MET exon 14 mutations in non-small cell lung cancer – A systematic review and meta-analysis. *Lung Cancer*. 2018;123:76-82. 2. Data on file. Novartis Calculation. Koster Health. *CancerFact*: lung (non-small cell) metastatic stage IV incidence and newly recurrent. Updated December 15, 2019. my.khapps.com 3. Aris ML, et al. EGFR exon 20 insertion mutations in lung adenocarcinoma: prevalence, molecular heterogeneity, and clinicopathologic characteristics. *Mol Cancer Ther*. 2013;12(7):220-229. 4. Averb S, et al. MET Exon 14 mutations in non-small cell lung cancer are associated with advanced age and stage-dependent MET Genomic Amplification and e-RAF overexpression. *J Clin Oncol*. 2016;34(7):721-730. 5. Brachtman DE, et al. BRAF-mutations in non-small cell lung cancer. *Lung Cancer*. 2014;84(1):34-39. 6. Viala E, et al. KRAS-G12C mutation is associated with poor outcome in surgically resected lung adenocarcinoma. *J Thorac Oncol*. 2014;9(10):1513-1522. 7. Doreau G, et al. Natural history and molecular characteristics of lung cancers harboring EGFR exon 20 insertions. *J Thorac Oncol*. 2013;8(2):179-184. 8. Schelller M, et al. EGFR mutation subtypes in NSCLC and associated co-occurring mutations in other oncogenic pathways. *J Thorac Oncol*. 2019;14(4):606-616. 9. Shao M, et al. Management of advanced non-small cell lung cancers with known mutations or rearrangements: latest evidence and treatment approaches. *Thor Adv Respir Dis*. 2016;10(2):113-129. 10. Vichitvej A, et al. Oncogenic and drug sensitive MET/RET rearrangements in lung cancer. *Nat Med*. 2013;19(11):1463-1472. 11. Gerson HJ, et al. Genomic testing and treatment landscape in patients with advanced non-small cell lung cancer (NSCLC) using real-world data from community oncology practices. *J Clin Oncol*. 2019;37(15 suppl):1585-1585. 12. Griesinger F, et al. Biomarker testing in non-small cell lung cancer in routine care: Analysis of the first 3,717 patients in the German prospective, observational, nationwide CRSP Registry. *Lung Cancer*. 2020;115(2):174-184. 13. Gulermez ME, et al. Genomic profiling of advanced non-small cell lung cancer in community settings: gaps and opportunities. *Clin Lung Cancer*. 2017;18(6):451-459. 14. Wernge MM, et al. A national assessment of diagnostic test use for patients with advanced NSCLC and factors influencing physician decision-making. *Ann Health Drug Rev*. 2020;13(3):110-119. 15. Yu TH, et al. Multiple biomarker testing: time consumption and completion rates with single-gene tests and investigational use of OncoPrint Dx Target Test for advanced non-small cell lung cancer: A single-center analysis. *Clin Lung Cancer*. 2019;20(1):20-29. 16. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Non-Small Cell Lung Cancer V.5.2021.

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to transform even further the standard of care throughout the patient health journey while also strengthening its AI-driven genomic and clinical data platform. Both companies have long been driven by generating and accessing large databases and applying a variety of data analytical techniques to derive insights about patients' health. We noted especially Sema4's focus on patient-centered health intelligence. Given this activity, we contacted Sema4 about addressing how the long-term plans for the company will increase its clinical presence while maintaining its technology prowess.

Along these lines, we put a set of questions to Isaac Ro, CFO at Sema4, with a focus on three topics – the platform of algorithms, healthcare partnerships, and the patient's journey. We approached Sema4 on learning of the deal to acquire GeneDx. As you read on, you'll see we covered that news as well as a host of other topics during our discussion!

Q. How does Sema4's recent acquisition of GeneDx add to Sema4's platform for a more comprehensive database? For example, novel algorithms or capabilities to harvest data from the clinic?

A. A couple of foundational capabilities are needed to build a platform of algorithms. One of them is access to extremely high-resolution genomic data. Today, we are at the point where genetic testing is a rapidly growing industry that's been enabled by the advent of Illumina's NextGen sequencing technology. The application of that technology, however, tends to be very narrow in a clinical context, meaning that many scientists and physicians tend to look only at a handful of genes, sometimes only one. And we, of course, know that many other scientists and physicians would want to look at the entire genome if they had all the relevant information. Today, we are moving towards a whole genome analysis, but we are not quite there yet.

We are in this interim phase of genome exploration that may turn out to be very long lived, namely, understanding the exome – the encoded portion of the genome. What makes GeneDx special is that they have perfected the commercialization of clinical exome analysis better, faster, and cheaper than any other company. This gives us an engine for acquiring enormous amounts of genomic data at the exome level. To date, GeneDx has sequenced over 300,000 exomes – nobody's done anywhere close to that amount. That is the primary asset in the deal.

The second piece of the GeneDx value stream, the massive repository of exome data they've assembled, can be very quickly subsumed into our existing database and platform of algorithms. Basically, it's like putting high octane fuel into

a fighter jet. We are going to have a whole new level of scale of data and analytical power. Taken together, we view GeneDx's capabilities and exome records as "hidden" assets that give us this turbocharged trajectory on our platform. This has been a long term trend moving thing and it is exciting that we're at another point of market inflection relative to where we've been over the last 20 years.

Q. What is Sema4's strategy to integrate molecular diagnostics data with patients' clinical data?

A. There's a tendency to assume that technology is, by itself, the key to making all this happen. But then there's, of course, implementation, which in healthcare is very difficult, especially when you have something that's distinctly different and clearly breakthrough. It takes years for adoption to play out in the hands of everyday physicians and patients.

"To date, we have partnered with four health systems, all of whom share the following enabling characteristics. First, they are integrated payer and provider systems, which makes it a easier for them to effect change. Second, they are already users of advanced genomic technologies, so this is not a new thing for them in concept. And third, and this is important for us, they're willing to share patient data with us in a collaborative way that most partners do not typically see."

How do you crack that code? I think one of the brilliant things that Eric did in conceiving Sema4 was to change our go-to-market strategy typically seen in this industry. If you look over the last 15 or so years, we see a successful industry of companies built up with basically the same playbook – set up a lab with a cool test that provides breakthrough insights in, say, oncology, then hire a group of salespeople, 50 to 100, of specialists who target the top 20% or so of early adopter oncologists. They go to them and say, "Hey, how would you like to ride the wave of the future?" In doing that, you can get to a very nice level of scale; so, we now have a dozen plus publicly traded companies – most are smaller cap, most have revenue less than a couple hundred million – respectable but limited.

Take cancer, for example – 80% of cancer patients are not sent to an academic setting; they're sent to a community hospital. For that 80% of people, the access to technology is still limited, not because technology isn't good, but because access to quality care beyond the technology.

Instead, Sema4's strategy is to approach a specific group of health systems who fit criteria that we think make them perfect partners for us. We say, "Let us be your collaborator. Let us be your partner. It's not going to be a traditional vendor customer relationship. Let's work together mutually to invest resources in time and people to bring this to life."

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When you hit all three characteristics, it's super exciting and we've achieved that with these four healthcare systems. And of course, Eric (Schadt, Sema4 CEO) would tell you that we always approach these counterparts with creating a partnership with a research-driven mindset being our key offering to them. Many of these health systems are premier institutions, but they are not necessarily among the top decile of NIH grant recipients. They have ambitions to be bigger research institutions, but they may not have the ability to do it themselves. We can catalyze that, and that resonates with their missions.

Q. Centrellis, Sema4's health intelligence platform, appears to be core to Sema4's capabilities. How will Sema4 be powered up by access to GeneDx data and Centrellis capabilities?

A. Centrellis combines several important capabilities that, together, make the platform special. Keep in mind – it's not just the technology component; it starts with people and talent. We have over 160 computational biologists, people with MD, PhD level degrees who sit at the core of the platform to curate, annotate, and process the data inputs. If you've spent any time with healthcare data, you learn quickly that it tends to be dirty, inconsistent, and not easily manipulated and analyzed. And of course, while AI is an incredibly powerful tool, it's still the case of "garbage in, garbage out." If you don't have clean, well-curated, well-annotated data, then what AI can tell you is very limiting. You still need world class scientific know-how and capability that sits on

top of your cloud and your computing resources, especially as cloud storage and computing power is becoming more and more available, almost as a commodity.

Along with NGS, we are riding powerful technological tailwinds, but my point is that you need people to harness it. So, say now you have the people and the technology – the third thing you need is access to high-quality data. In general, access to patient data is tricky because there's a lot of data for purchase in the marketplace, but those data are typically limited by clinical context. It's one thing to have a snapshot of someone's genetic code but with no other information about their diagnosis, their treatment history or future, or physician interpretation with a proper diagnosis. Without all those things, it's just information. So, in an ideal world, you would want not only a snapshot of patient data, but you would also want those data over a period of time.

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Access to longitudinal data sets becomes very important. The only way we see to gain access to these data is to have a high level, trusting relationship with the provider. Our go-to-market strategy for the health systems starts with building a relationship with the physician – our user. You need to have that relationship for the data to be dimensionalized and, of course, scalable over time. So those are the three things we've done to make Centrellis special. Some companies can circle one or two of those three concentric circles in the Venn diagram, but no one else currently covers all three, and certainly not at the necessary scale.

Q. As for partners, are you talking to systems that offer multi-state coverage?

A. Experience is extremely important to us. Experience brings intangibles that start with respect for the privacy and the sanctity of the data we host. In fact, we use the word “access” because we don't believe we own the patient data. Data belong to the patient. We are privileged to have access to it, and that requires trust, it requires security, it requires investment in that security.

We make sure that the physician and the user experience are governed by those values. We put ourselves in the shoes of a patient. In the case of women going through a pregnancy, we provide

them tools that can be accessed on a smartphone or with a simple web interface, all those soft touch things that make the experience better with educational tools.

We engage not just in education for the the patient, but also the physician. Physicians are increasingly overwhelmed with new information and technology; they need help understanding how to use these tools (information and technology) as well as the circumstances for which tools are applicable. We serve those purposes while keeping security and a research collaboration mentality foremost in mind.

That's why we've been able to get this unfettered, extremely rare level of access with high rates of consent. When we ask patients for consent to access their medical records, they say yes at unusually high rates because we've put all this together over time in a way that resonates with the health system partnership approach.

Our engagement with health systems is different in many ways, not just the fact that it's not a traditional sales call. But it's also typically from the top down where our CEO, Eric, is going to the CEOs of these health systems and saying, “Let's architect something that allows you to accomplish a big part of your agenda as a health system administrator and work with you there from the top down.” When you do that at you get a different level of buy-in. Once we've got that level of buy-in, it becomes a very different relationship than just, we love our sales reps.

Now, of course, every department in a health system is different and has different agendas. You've got to create not just sponsorship from the top down, but also champions within, at the department level. When you do that, you come up with specific scopes of work, for example, in women's health or cancer or rare disease.

That's how we put these relationships together. In doing all that, it allows for a much higher level of trust and collaboration out of the gate. As the CFO, I can tell you in numbers that trust can be expressed by how health systems are investing their resources – person hours and, in some cases, millions of their own dollars. Most health systems are non-profit, so this is a non-trivial investment for them.

Q. What are the top two or three lessons learned from partners that Sema4 uses to improve its performance, its platforms?

A. It is important to remember we are at the infancy of this industry's evolution. When we talk about partners, we don't just call them partners, we think of them as learning-based partnerships. We're both in it, not only to make an impact, but also to learn. The nature of the industry is not a

one-size fits all model by any stretch, and it won't be anytime soon. If you've met with one health system, you've met with one health system. I liken it to a systems integration type business model. Think of it as a McKinsey or a Deloitte coming in and doing a big ERP upgrade to a global company.

It's that kind of a close relationship that's consultative in nature but iterates over a long period of time with a dedicated hub and spoke team mindset. You do all those things because you just don't know exactly when and how it's going to land. And the whole thing will happen in chapters, but the whole book end to end is hard to write. When we think about where we are today in 2022, I suspect that in two or three years, we may see developing a small, medium, and large way to define how things are different.

There's been an extraordinary uptake and incredibly encouraging levels of feedback on the impact that we're already having. We talked about our third quarter earnings call about the first six months with the Northshore Health System in Chicago and their extraordinary rates of compliance for cancer risk assessment that are multiples of what they had before they partnered with us. They've been doing this for years, so there is clearly a sea change. We'll see how well it sticks, but we feel good about the progress so far.

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Q. As for partners, are you talking to systems that offer multi-stage coverage? Or is Sema 4 currently targeting at a local level for partnerships? What do you see in terms of regional differences?

A. Let's go back to the comment I made about the market structure of health systems, they're all different. But you can place categories at either end of the spectrum.

At the one end of the spectrum, you have, say, 50 or so of the nation's strongest, most sophisticated health systems who are very well resourced and very sophisticated in what they're doing in this field. They might ask, “What about working with Sema4?” They may say, “What they're doing is cool, but we can do what they do ourselves, or maybe we already are. So, why would we need a commercial partner?”

At the other end of the spectrum, you're going to have a large tail of community health systems that, ▶

even if they wanted to implement something like this, they just don't have the ability to do it. It's just too heavy of a lift.

Like any distribution curve, most opportunities lie for us in the middle range, where you find large, integrated payer provider systems that use genomics and are willing to share data. If your company fits that trifecta, then you are probably a good partner for us to explore as a partner. That middle chunk is a universe of health systems that we think is more than big enough, certainly multiples bigger than we can realistically service anytime soon. For us, this business growth opportunity goes about as far as the eye can see, and so that's great. We don't expect to be the ideal solution for everyone. That's not how healthcare works and that's not our ambition, at least not any time soon. Maybe someday down the road!

We are heading in the right direction. We've also just taken the business model in this industry and turned it on its head, and we'll head toward this universe of companies that look and feel similar to where we are. I remind investors and external audiences that Eric, as our conceived of the business as a data-first culture, and that's who we are today.

We have resources and assets attractive to this universe of companies, including things like a lab that we're very proud of and a franchise that is very strong. We've got a huge sales force that's done a great job, going toe to toe with the other public companies and diagnostics outfits. But we don't aspire to be purely a diagnostic company over time. We want to be a data company that happens to have a great diagnostic business, not the reverse. That's a stark contrast to what you see elsewhere in the industry, where it's mostly diagnostic companies who have grown up and done very well and now are trying to become data companies.

I would submit that it's probably harder to do the former. We'll see how it all plays out, but there may possibly be convergence from opposite directions. And then on top of all that, you have data companies who have good know-how on software and analysis, but maybe don't understand genomics deeply enough. The genomics piece, as evidenced by the GeneDx deal, is a market that is moving and evolving so fast that it's difficult to be a primary player with primary know-how in the wet lab and still claim that you can harness all technology well.

We are moving to the exome world and will eventually move to the whole genome world. We don't want to be a company that doesn't have a primary hand in making transitions happen and is just a customer of the data feeds – that's going to be a limited way to live. We know about great data and software companies out there, but we still think you need to have a fully vertically integrated business

model – you need the lab, you need the data scientists, you need, of course, the data platform, and you need the relationships with health systems. You need all of those pieces to do what we're doing.

Q. To what extent has Sema4 made progress in extending and keeping in the loop with patients? Does Sema4 continue to receive information throughout the patient journey for treatments and outcomes? The critical point at the end is, what is the outcome of that patient? And how does that feed back into the Sema4 platform?

A. We very much believe in being with a patient on a relational basis through a healthcare journey – and that is part of the reason we started with women's health. Women and potential parents come in seeking to conceive through a fertility process that requires carrier screening. What we do best is support those who go through that fertility process and progress to a pregnancy, then continue that support with newborn screening and documenting the mother's health journey.

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For the newborn, you might have a need to test for rare disease, which is where GeneDx fits in and why GeneDx is so valuable. GeneDx is by far the market leader for clinical exome sequencing of newborns to screen undiagnosed rare disease. Rare disease is not as rare as implied by the name; any one condition may be a small percent of the population but the cumulative effect of the variety of rare diseases prevalent in a population can be significant.

Currently, many cases go undiagnosed because technologies were not available (for example, sequencing and better annotation). We're now entering this amazing era where testing is potentially available to everyone. We want to be a big part of driving that forward and extend our relationship with the family into the newborn's life. We started to evolve our marketing to say that we're a family health company post transaction,

supporting multiple members of the family, not just the mother. If we can do that writ large, you can imagine a database at population scale across large catchment areas where you have families and extended families all connected into the network.

Here's where the value to drug discovery becomes exciting. Instead of searching for proverbial needles in a massive global haystack – the 20 children across the world who have this to one diagnosed disease – we prefer to say, "We found a case in this one area and started to look at the genomic profiles and medical records of the people where this child lives." Can we find patterns in the noise? Can we learn something about a rare disease that way?

We aim to follow patient journeys writ large over time and across populations – treatment, diagnosis to gain longitudinal perspectives. We want to have that level of dimensionality in the rare disease context for an individual as well as at population scale. This allows us to talk to drug companies about clinical trial enrollment, pipeline development – things that you could not do before are now possible. That is, in our estimation, an extremely powerful catalyst for value creation and for potential treatments where none exist today.

Q. In line with Sema4's focus on family health, could you discuss Sema4's plans for genetic counselling and how this capability will be coordinated with healthcare partners?

A. Let's step back and put ourselves in the shoes of a physician, that feeling of being overwhelmed with all this data and what does it mean? Even with a well-curated AI-powered data platform like Sema4's platform, the physician will still take delivery of a complex information packet that may require handholding in some cases. We decided to offer a value-added service to give physicians more tools to enhance their experience, as well as the patients. And increasingly, those tools are made available through a web and smartphone interface, because that's just the way people operate these days, especially when you think about what's changed during the pandemic. Telehealth has taken off.

This trend has been accelerated by the pandemic. Healthcare can now reach more patients directly with high resolution feedback on patients' genetics. We see it as an area of continued investment for us, and another reason why we believe you need to have genetic counselors and the relationship with the health system in this fully vertically integrated business model.

We're exiting a phase of infancy in the clinical NGS market where companies like Illumina have done incredible things. NGS has given rise to a number of companies that are doing a lot of good

for patients. In cancer, in women's health, those are the most mature areas today and we are starting to see different types of innovation in these and other areas.

Tests are starting to converge. Several companies have very strong offerings in tumor profiling, Noninvasive prenatal testing (NIPT), and hereditary risk assessment. Now the question becomes, how do you have a greater impact clinically? Many companies tend to focus on price, service, and quality, but these dimensions start to be taken for granted. Instead, we asked, "What about the physician experience? What about the patient experience? What about clinical context? What about actionability?"

Diagnostic testing has been around for a long time but historically, a diagnostic test identified the patient's condition but not enough depth to indicate a treatment – precision medicine. The doctor needed to adjudicate actionability. And now, the equation's flipping where the mass of data is more than a doctor can digest. That's why genetic counseling becomes important and why companies like us become more relevant. It's an exciting time to start thinking about the evolution of business models and we see ourselves as pioneers in market evolution.

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Q. Both companies, GeneDx and Sema4, have genetic counseling. How will these capabilities be merged? How will this function be leveraged by your healthcare system partners?

A. We expect the completion of the Sema4-GeneDx deal in Q2 2022. During this period, we are highly constrained by what we're allowed to do when it comes to integration. We can do a lot of preparation, but we can't take a lot of action.

So, in answer to that question, I can say that the combined company's goal would be to drive clinical exome sequencing into the market as quickly as possible. We're not alone in that vision.

Other companies are starting to do it, but we think we're going to have a huge running start. As a combined company, our attention will focus on how to support the physicians and patients with this quantum leap in data volume and content.

We see that genetic counseling will only become bigger and more diversified – for example, GeneDx in the rare disease market and Sema4 on the women's health side. We are both somewhat small but growing players in oncology. Those three therapeutic areas are where we seek to build out our genetic counseling capabilities. We come with critical mass on both sides, so that gives us a huge opportunity to stay in the lead once we're done. That's the best I can say today. We're super-excited to see how it plays out once the deal closes in Q2.

Q. Sema4 has an app available for their customers. Is that app going to be linked to social media sites? How do you foresee using telehealth for feedback or for pushing information out to patients?

A. We see ourselves as a data company more so than anything else. We've learned that all manner of data – genomic, imaging, wearables, or social media – can be taken together as highly instructive for creating the value of an algorithm for healthcare purposes.

We are open to exploring different ways to build relationships with patients and physicians over time. Again, we always see the physician as the primary entity that we need to service. They're the ones that adjudicate and make decisions on behalf of patients. We want to enable physicians in a way that works for them while also having a relationship with patients, whether in-office or via our apps.

It's worth maybe spending a minute on the Sema4 culture. We're based in Stamford (CT) as a spin-out of the Mount Sinai Health System, New York City. Our team of developers and software engineers are based in New York City in the Union Square Area, the Silicon Alley where many tech companies are planting flags. Our culture is to support that group to be strongest at what they do best. That commitment is a testament to Eric's vision of how we want to put together not just technology, but also the people.

I'm on the board of BioCT, a non-profit biotech industry group in Connecticut. We've partnered with the Tri-State Area to leverage the incredible things New York City is doing to bring the life science industry to Manhattan and the surrounding area. We want to be part of that growth as a local company, with roots in Connecticut and New York, and soon to be in the Gaithersburg area in Maryland with GeneDx.

I would just like to say one last thing, which is to acknowledge that we know we're not the only

ones working on cool stuff. We are riding a wave on a sea change in the entire healthcare ecosystem, from global drug companies leaning hard into the ways these technologies can improve drug development to a cottage industry of software companies – all trying to capitalize on digital health and moving towards this future state driven by data, relationships, and platform technologies.

And while we're vertically integrated, we're also seeking those who work with all ranges of constituencies for opportunities to partner. Right now, we're working first and foremost on closing the Sema4-GeneDx deal. In the meantime, our corporate development team is busy looking for other entities with whom we can work. Stay tuned. [#SPM](#)



Isaac Ro

Isaac has 20 years of financial leadership and experience, with a strong focus on the medical technology and life sciences space. As Chief Financial Officer (CFO) at Sema4, Isaac is responsible for leading all aspects of financial strategy, management, and planning.

Prior to joining Sema4, Isaac served as CFO of Thrive Earlier Detection Corp., a company dedicated to incorporating earlier detection of cancer into routine medical care. In this capacity, he led the sale of Thrive to Exact Sciences Corp. (Nasdaq: EXAS) for \$2.15 billion after rapidly scaling the company and raising \$257 million in a Series B financing.

Before Thrive, Isaac led the U.S. Medical Technology team at Goldman Sachs where he covered the Life Science Tools, Diagnostics, and Medical Technology sectors. He also held a similar role at SVB Leerink. His career as an equity analyst spanned 16 years, over 60 publicly traded companies, and numerous IPOs and equity financing transactions.

Isaac also serves on the Board of Directors for BioCT.

He holds a BA in History and was pre-med at Middlebury College.

Reference

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